IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF OKLAHOMA

UNITED STATES OF AMERICA, and the States of CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW HAMPSHIRE, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VIRGINIA, WASHINGTON, WISCONSIN, the DISTRICT OF COLUMBIA, and the CITY OF CHICAGO, Plaintiffs, *Ex rel.*, JAMIE SIEGEL, M.D., Plaintiff-Relator, v. NOVO NORDISK, INC., Defendant.	**SECOND CONSOLIDATED COMPLAINT** **CASE NO. CIV-15-114-PRW** **JURY TRIAL DEMANDED** FILED MAY 11 2020 CARMELITA REEDER SHINN, CLERK U.S. DIST. COURT, WESTERN DIST. OKLA. BY _____, DEPUTY

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This is a Consolidated Complaint brought by the State of Washington ("Washington" or "State") in intervention to recover under the State's Medicaid Fraud False Claims Act, Rev. Code Wash. 74.66 *et seq.* (hereinafter "RCW") and the Fraudulent Practices Act, RCW 74.09.210 and by Relator Jamie Siegel, on behalf of the other named plaintiff governments. In sum, Novo Nordisk, Inc. ("Novo") orchestrated a kickback and off-label scheme to promote one of its prescription drugs – NovoSeven® – resulting in the submission of false and fraudulent claims to all named government entities.

I. INTRODUCTION

1. Hemophilia is a rare, life-threatening, genetic bleeding disorder in which the blood does not clot normally. Persons afflicted with this disease bleed longer than others after an injury because they lack proteins in the blood called clotting "factors" that are required for normal blood clotting.

2. Patients with hemophilia also bleed internally, especially in their knees, ankles, and elbows, where external pressure cannot be applied, causing permanent damage to organs and tissues and resulting in deformed joints, limited mobility, and chronic pain. For individuals with hemophilia, unchecked bleeds can lead to serious health problems, such as immobility, neurologic damage, and death. Hemophilia, which is incurable, affects approximately 20,000 people in the U.S., mostly boys and men.

3. For people who do not have hemophilia, blood factors work with platelets that form in the bone marrow and proteins in body tissues to form clots that stop bleeds. In the 1960s, doctors learned to isolate these missing factors from the plasma of normal individuals and infuse them into the bloodstream of hemophiliacs to help them clot

normally. In the late 1980s, pharmaceutical companies developed methods to manufacture factors using recombinant techniques to avoid the transmission of blood-borne diseases like HIV and hepatitis C from human donors.

4. Of those patients born with hemophilia (deficient or absent factor VIII or factor IX), approximately 15-20% will develop an antibody, called an inhibitor, to their deficient or missing factor. This inhibitor will prevent the corresponding infused factor from clotting and render it ineffective, so that the patient once again cannot stop bleeding. For this reason, persons with hemophilia who have an inhibitor ("PHIs") often need a special product called a bypassing agent to stop painful bleeds.

5. Enter the "Battle of the Brands." This is a marketing slogan used not for the sale of cars, clothing, or cosmetics; it is a phrase used by marketers at Novo, one of the world's largest drug companies, to describe a multi-pronged – and highly illegal – effort to induce this discrete and vulnerable population of PHIs to use Novo's bypassing agent NovoSeven®,[1] as opposed to the other bypassing "brand," FEIBA, or Factor Eight Inhibitor Bypassing Agent, which is manufactured and was formerly sold by Novo's competitor Baxter International Inc. ("Baxter").[2]

6. Novo's business plan was based on three objectives: (1) maintain the market share it had; (2) capture market share from FEIBA; and (3) expand the market for NovoSeven® the only way possible – given the very few PHI that needed it – by

[1] NovoSeven® and NovoSevenRT® are used interchangeably in this Consolidated Complaint; both formulations have the same label indications.

[2] FEIBA is now sold by Takeda Pharmaceutical Company Ltd.

increasing dose size and frequency. To accomplish these business goals and overcome its product's fundamental inadequacies, Novo (1) unlawfully promoted NovoSeven® for unapproved uses; (2) tainted the medical literature by funding, creating, and shepherding numerous articles and education materials that recommended off-label uses and downplayed NovoSeven®'s weaknesses and safety risks; and (3) paid kickbacks to anyone who could influence the treatment of a PHI – the patient, the patient's family, the physician, and the pharmacy. Novo also refused to perform certain studies on the safety and effectiveness of NovoSeven® because it didn't want to give away free drugs for the study and it was worried that lower, safer doses would be shown to be effective – in other words, because it would make less money. All of this conduct violated the federal False Claims Act and similar state and municipal false claims act statutes, among other laws.

7. The marketing worked: "Between 2000 and 2008, off-label use of [NovoSeven®] in hospitals increased more than 140-fold, such that in 2008, 97% (95% CI, 96% to 98%) of 18311 in-hospital uses were off-label." Logan *et al.*, Ann Intern Med. 2011 April 19; 154(8): 516–522. Off-label sales continued to increase while government and third-party payors paid the price – to the tune of billions of dollars.[3]

A. NOVO'S SCHEMES

8. NovoSeven® is approved by the Food and Drug Administration ("FDA") for PHIs to treat acute bleeding episodes or to prevent excessive bleeding during surgical

[3] *See* Section VIII.

interventions or invasive procedures.[4] NovoSeven®'s package insert also directs injections at a dosage of 90 μg/kg of NovoSeven® every 2 hours until the bleed has stopped.

9. The FDA has *not* approved NovoSeven® for doses higher than 90 μg/kg, nor is NovoSeven® approved for use on a routine basis (*i.e.*, several times per week or daily) to *prevent* spontaneous bleeds from occurring in the first place – a treatment strategy referred to as "secondary prophylaxis" or "prophylaxis"[5] or just "prophy" as Defendant's marketers refer to the usage. NovoSeven® is not approved for *any* uses for which there are not "proper" instructions on the label.

10. In contrast, as Novo was well aware, its competitor Baxter sought and gained FDA approval for FEIBA's prophylactic indication after submitting data collected during two large, well-controlled studies and based on Good Clinical Practice (GCP) criteria. FEIBA is also less expensive to use than NovoSeven®. Moreover, FEIBA is more suitable for prophylaxis because it has a significantly longer half-life than NovoSeven®, meaning that it stays in the body longer than the Novo product and requires fewer administrations – only three times a week, instead of daily or even multiple times a day. While Novo's internal documents – including sales plans – admit these and other product deficiencies, Defendant still tasked its sales force to disrupt stable

[4] NovoSeven® package insert available at https://www.fda.gov/media/70442/download.

[5] "Primary prophylaxis" refers to preventive treatment of toddlers with FVIII or FIX to avoid the initial bleeding events that result in long-term joint damage and is not at issue in this Consolidated Complaint.

medical regimens by working to convert vulnerable patients to NovoSeven® for usages and dosages that were unapproved, outside the label, and dangerous. Defendant's own documents reflect that it engaged in this conduct even where it knew FEIBA was working in specific patients.

11. In all of its marketing efforts, however, Defendant never disclosed – indeed it concealed – what it knew all along: Novo did not secure a prophylaxis indication for NovoSeven® because it could not demonstrate that NovoSeven® was safe and effective for this use. The data Novo submitted to the FDA for the prophylaxis indication was based on a study, referred to as 1505, of 22 patients evaluated for a change in bleeding episodes from baseline, during, and for three months after prophylaxis treatment. That study was later the subject of an article authored by Dr. Barbara Konkle (the "Konkle Study").[6] These results did not provide sufficient evidence for the FDA to expand NovoSeven®'s indication. Novo decided not to pursue the Phase III study that FDA had requested to obtain an indication for prophylaxis. Instead, Novo used the Konkle study in marketing its product for prophylaxis without expressly disclosing to doctors or patients that the FDA had rejected this study as support for an actual indication for prophylaxis.

[6] B.A. Konkle, L.S. Ebbesen, E. Eehardtson, R.P. Bianco, T. Lissitchkov, L. Rusen and M.A. Serban, *Randomized, prospective clinical trial of recombinant factor VIIa for secondary prophylaxis in hemophilia patients with inhibitors, Journal of Thrombosis and Hemostasis*, 5:1904-1913 (2007). Notably, authors L.S. Ebbesen and E. Eehardtson were both Novo employees at the time the article was written, and the article's listed conflicts of interest include other Novo employees who assisted in trial design, trial logistics, data analysis, and manuscript preparation.

12. Similarly, Novo was unable to obtain FDA approval for higher doses because it never demonstrated that a higher dose of NovoSeven® – 180 μg/kg to 300 μg/kg – was superior to the approved dose of 90 μg/kg for acute bleeds. The absence of scientific support for higher doses, however, did not stop Novo from promoting them. Of course, the real value in pushing a higher dose was that Novo could make more money.

13. In order to increase sales, Novo resorted to three illegal schemes: off-label promotion, a fraudulent publication strategy, and kickbacks.

1. Novo's Off-Label Marketing

14. If Novo's bypassing agent were restricted to just acute bleeding episodes and control of bleeding during invasive procedures and surgery in the small market of PHIs, its revenue stream would be limited. By contrast, a patient using NovoSeven® for prophylaxis was worth nearly three times more to Novo than a patient who took the drug to treat acute bleeds. A prophylaxis patient was worth on average $2 million per year in comparison to a non-prophylaxis patient at $670,000. Indeed, as one OIG report found, some patients used several million dollars' worth of NovoSeven® a year.[7] If patients were convinced to use higher doses of NovoSeven®, more product would be sold and Novo's profits would increase.

[7] *See* Review Of Medicare Payments For NovoSeven Coagulation Factor VIIa To Indiana Hemophilia And Thrombosis Center, Inc. From January 1, 2008, Through December 31, 2009, (HHS OIG 2011) (reporting that Medicare paid $46,783,961 for NovoSeven used by six patients over a two-year period) (available at https://oig.hhs.gov/oas/reports/region5/51100027.pdf.).

15. Driven by self-imposed revenue goals, Novo embarked on a no-holds-barred prophylaxis marketing campaign – the Battle of the Brands, a war cry that energized sales representatives and other marketers and distracted them from any critical thought about a scheme that endangered human life while causing the medically unnecessary expenditure of government and other third-party payor dollars. The Battle of the Brands was a marketing slogan whose very development was an acknowledgement that Novo could not sell its product on the basis of medical rationale alone. And it was a marketing slogan that created the false illusion that the Novo and Baxter products were fully interchangeable, the only distinction being the brand.

16. Abundant internal documents show that, year after year, Novo drummed into its sales staff the core connection between off-label marketing, kickbacks, and direct marketing to patients, who played key roles in drug choice. Novo incentivized its sales force with bonuses for "off-label" prescriptions and for conversions of PHIs from FEIBA use to use of NovoSeven®. In 2008, a sales representative would earn $500 for every FEIBA patient that was converted to NovoSeven®, $200 more if the conversion took place at a "Key FEIBA Center" or "KFC." By 2011 the reward was a minimum of $2,000 per conversion up to a maximum of $10,000 per representative. These large payments to sales representatives and managers were warranted because, as Novo recognized, "[c]onversions are the most valuable source of brand revenue," with an average annual value of $600,000 each conversion.

17. Novo also took steps to establish a larger 270-μg/kg dose as the standard of care through off-label marketing. For example, in 2011, it held an Advisory Board of

internationally renowned hematologists in Madrid, Spain to promote 270 μg/kg dosing and dosing "optimization" as well as obtain feedback from the advisory board as to the strengths and weaknesses of that promotional campaign. Over and over, the advisors cited the "lack of clarity" on effective dosing and that "[n]ot enough was known about the safety of dosing at 270 μg/kg more frequently" or treatment intensification. Novo has never provided that requested information, despite continuous marketing for higher doses.

2. Novo's Publication Strategy

18. In addition, Novo implemented a publication strategy that produced purportedly objective scientific articles promoting the "key messages" related to NovoSeven®'s efficacy for prophylaxis and high-dose use. The physicians who signed as authors of these articles were paid honoraria for use of their names. As a result, the medical literature was littered with publications that were thinly disguised marketing pieces aimed at establishing an "off label" standard of care. It did so absent any label instructions for the "proper" use of NovoSeven® for prophylaxis or at higher doses, or even any study providing convincing evidence of the effectiveness of such uses.

19. Novo also pushed off-label uses of NovoSeven® to physicians through Continuing Medical Education ("CME") programs it developed, through the efforts of its marketing personnel and the company's Medical Science Liaisons (MSLs), who were tasked with coordinating on sales calls with sales representatives and physicians to promote off-label uses of NovoSeven®.

3. Novo's Kickback Scheme

20. Finally, Novo engaged in several tactics that violated the Anti-Kickback Statute, the Washington State anti-kickback statute, and the Beneficiary Inducement CMP, including:

- Paying kickbacks to physicians to prescribe NovoSeven® for on-label and off-label uses via the Hemostasis and Thrombosis Research Society Registry ("HTRS Registry"), which was sponsored by Novo to fulfill FDA-required post-marketing data collection of NovoSeven®;
- Paying well known hemophilia physicians to sign manuscripts that were actually written by Novo employees and/or influenced by Novo editors, which were submitted to leading hemophilia medical journals, touting "data" based on opinion, poorly controlled studies, registries (including the HTRS Registry), and a compilation of case reports supporting the use of NovoSeven® for off-label purposes, specifically prophylaxis and at higher doses;
- Paying high-profile hemophilia doctors, designated as Key Opinion Leaders ("KOLs"), to use their influence – via journal articles, speaking events, and participation in educational events – to persuade health care providers, patients, hemophilia advocacy groups, hemophilia professional societies and home health companies specializing in hemophilia care to use NovoSeven® off-label for prophylaxis and at higher doses;
- Sponsoring and hosting "all-expenses paid" events for PHIs, such as camps for children and summits or "weekend retreats" for adults and adolescents, at which Novo promoted the use of NovoSeven® for off-label purposes, specifically prophylaxis and at higher doses;
- Paying well known hemophilia physicians to "mingle" and speak at these patient events;
- Providing other gifts and benefits to PHIs; and
- Paying high-profile adult PHIs who use NovoSeven® for prophylaxis to promote such use to other patients, including through patient literature disseminated by Novo and/or at hemophilia camps for children or weekend retreats for adult patients, which were supported by or paid for entirely by Novo.

21. One component of Defendant's kickback scheme was particularly unusual: Novo promoted and paid kickbacks directly to patients and their caregivers. This scheme was executed in conspiracy with RxCrossroads, a subsidiary of Omnicare – a company

whose profits have routinely been enhanced through fraudulent schemes to obtain precious government healthcare dollars. Though subject to a corporate integrity agreement ("CIA") as a result of its lawless conduct,[8] Omnicare's internal counsel approved an RxCrossroads contract with Novo, certifying it as free from violations of the federal Anti-Kickback statute, even though the contract – on its face – calls for RxCrossroads to be the conduit for kickbacks to flow directly to publicly and privately insured patients – including cash loaded onto credit cards.

22. The contract between Novo and RxCrossroads called for gifts and benefits to flow to patients through three programs: SevenSECURE, SevenSTART, and SevenASSIST (referred to collectively as "SevenSECURE"). All three were Defendant's branded programs and all three were available only to Defendant's target market – PHIs. Internal Novo documents make clear that Novo targeted the limited inhibitor market – perhaps as little as 1,500 congenital PHIs in the United States – because it wanted to bestow benefits on existing users to keep them and it wanted to entreat users of FEIBA for what it repeatedly called "conversion." The SevenSECURE program was also one of several mechanisms that Defendant employed to collect patient-specific information so that marketers could target them on an individual basis.

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[8] *See* Amended and Restated Corporate Integrity Agreement between the Office of Inspector General of the Department of Health and Human Services and Omnicare, Inc. at https://www.justice.gov/sites/default/files/elderjustice/legacy/2015/07/12/omnicare_inc_11022009.pdf

23. Novo knew its entire relationship with RxCrossroads was violating the law, yet it did nothing. On July 29, 2014, Defendant's SevenSECURE brand manager Stacy O'Donnell engaged in the following email exchange with her counterpart at RxCrossroads, Luke Hemming:

> 9:17 AM from O'Donnell: "Can you confirm my knowledge? SevenSTART is not open to publicly insured patients?"
>
> 9:23 AM from Hemming: "There has never been a restriction on what kind of insurance a patient has. Do we need to institute one?"
>
> 9:27 AM from O'Donnell: "Not at this time. Thank you!"

24. Novo's gross misconduct was not limited to its relationship with RxCrossroads. It also channeled money through purported nonprofits that ran Novo-funded summer camps for children with hemophilia. Acting under cover, these gave Novo sales representatives direct access to patients for marketing purposes. The camps were staffed by Novo sales representatives, as confirmed by the sworn testimony of Jerry Hanson, a Novo sales representative: "I would say the majority of sales people went in various capacities to help administer at camp, to cook and clean up the mess hall and do whatever .... [T]he majority of my cohorts were always there when they had the camp."

25. Novo retained a New York ad agency to use patients, including some whose drugs were paid for with government healthcare dollars, to advertise – not the medical benefits of a NovoSeven® regimen – but the monetary benefits of a relationship with Novo, which meant all kinds of grants and funding. Defendant knew these benefits violated the Anti-Kickback statute. To enlist the cooperation of the patients in these ads,

Defendant tasked as many as three sales representatives to lobby each patient or his or her legal guardians through dinners, travel, and other remuneration.

26. Defendant even created a patient Consumer Council where patients or their guardians were paid "honorariums" of $750 a day and provided with free trips and meals for weekends with Defendant's marketing team for the ostensible purpose of improving delivery of healthcare to the hemophilia community – patients and their families. In fact, the information gathered was used to identify ways to increase the use of NovoSeven® and, thereby, the Defendant's revenue.

27. While Novo engaged in the foregoing schemes, it was well aware that using bypassing agents increases a patient's risk of a potentially fatal thrombotic event ("TE"). Such consequences are not merely a side-effect of the drug; they are a direct effect. The very purpose of this drug is to affect the coagulation of blood. If not enough is taken, the patient bleeds out; if too much is taken, the patient runs the risk of a thrombotic event. Indeed, this balance between blood-flow, bleeding, and coagulation is a delicate balance. Thus, correct dosage is critical. Yet, in furtherance of its false marketing narratives, Novo promoted the falsehood that any TEs experienced by PHIs were not related to the use of NovoSeven®.[9]

[9] *See discussion of* T Abshire and G Kenet, *Safety update on the use of recombinant factor VIIa and the treatment of congenital and acquired deficiency of factor VIII or IX with inhibitors,* Haemophilia, Sept. 2008, at 14(5):898-902 *infra* at Section VII.

28. Finally, as all this misconduct was ongoing, no fewer than sixteen of Novo routinely certified compliance with the very laws that Defendant was violating as part of a CIA it had entered with the federal government.

29. Plaintiff-Relator Jamie Ellen Siegel M.D. ("Relator") is a physician with certifications in Internal Medicine, Oncology, and Hematology with specialized training in Hemostasis and Thrombosis (the care of patients with disorders associated with excessive bleeding or clotting) as a fellow at Thomas Jefferson University Cardeza Foundation and in the Hemophilia Center there from 1987-1989. She has first-hand knowledge of Novo's deliberate strategies to promote off-label use of NovoSeven® for prophylaxis and off-label dosing regimens, which continues to this day, and the payment of kickbacks to secure prescriptions of NovoSeven® through documents evidencing the fraudulent scheme as well as inside knowledge of the pharmaceutical industry and, particularly, Novo, where she worked from 2008 to 2009.

30. Relator brings this Consolidated Complaint against Novo *qui tam* on behalf of the United States of America and on behalf of California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Virginia, Washington, Wisconsin, the District of Columbia (the "States"), and the City of Chicago, pursuant to the *qui tam* provisions of the Federal False Claims Act and similar state and municipal provisions and the provisions of the California Insurance Frauds Prevention Act, Cal. Ins. Code § 1871.7.

31. The State of Washington intervenes with respect to Relator's claims brought on behalf of Washington pursuant to RCW 74.66 *et seq*. The State of Washington also brings a separate claim under the Fraudulent Practices Act, RCW 74.09.210.

II. JURISDICTION AND VENUE

32. Relator brings this action on behalf of herself and the United States for violations of the False Claims Act, 31 U.S.C. §§ 3729-3733 and on behalf of the States and the City of Chicago for violations of the State False Claims Acts. Relator also brings this action pursuant to Cal. Ins. Code § 1871.7, the California Insurance Frauds Prevention Act. The State of Washington brings this action on behalf of the State's Medicaid program for violations of RCW 74.66 *et seq.* and the Fraudulent Practices Act, RCW 74.09.210. This Court has federal subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1331 and 31 U.S.C. § 3732 and supplemental jurisdiction over the counts relating to the State and municipal false claims statutes, the State of Washington statutory causes of action, and the California Insurance Frauds Prevention Act pursuant to 28 U.S.C. § 1367 and 31 U.S.C. § 3732.

33. This Court has personal jurisdiction over Novo Nordisk, Inc., pursuant to 31 U.S.C. § 3732(a), because Defendant can be found in and transacts business in this District. In addition, numerous acts prohibited by 31 U.S.C. § 3729 occurred in this District. 31 U.S.C. § 3732(a).

34. Venue is proper in this District pursuant to 31 U.S.C. § 3732(a) because Novo Nordisk, Inc. transacts business in this District and numerous acts proscribed by 31 U.S.C. § 3729 occurred in this District.

35. Relator's claims and this Consolidated Complaint are not based upon prior public disclosures of allegations or transactions in a Federal criminal, civil, or administrative hearing in which the Government is already a party, or in a congressional, Government Accountability Office, or other Federal report, hearing, audit, or investigation, or from the news media, as enumerated in 31 U.S.C. § 3730(e)(4)(A).[10]

36. To the extent that there has been a public disclosure unknown to the Relator, the Relator is the "original source" under 31 U.S.C. § 3730(e)(4)(B).[11] The Relator has independent material knowledge of the information on which the allegations are based and has voluntarily provided the information to the Government before filing this *qui tam* action based on that information. *Id.*

III. PARTIES

37. **State of Washington**, through authorized actions of its Attorney General, brings this action on behalf of its Medicaid program, agency and respective state interest. This authorization includes standing to bring this action under RCW 43.10.030, RCW 43.10.110, RCW 74.66.040, RCW 74.09.240 and RCW 74.09.210.

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[10] To the extent that conduct alleged in this Consolidated Complaint occurred prior to March 23, 2010, the prior versions of the False Claims Act are applicable (*i.e.*, 31 U.S.C. § 3730(e), as amended, October 27, 1986, and May 20, 2009).

[11] *Id.*

38. **Plaintiff-Relator Jamie E. Siegel** is a resident of Maryland. She is a graduate of the Medical College of Pennsylvania B.A.-M.D. program and is licensed to practice medicine in Pennsylvania. She is board-certified in Internal Medicine, Medical Oncology, and Medical Hematology. She is a contributing author of nineteen peer-reviewed published papers, twenty-one published abstracts, and seven book chapters. From 2001 to 2008, Siegel was a Clinical Associate Professor of Medicine and a Director of the Hemophilia and Thrombosis Center at Thomas Jefferson University. In 2005, she was the Chair of the NovoSeven Ad Hoc Committee at Thomas Jefferson University Hospital. She also was responsible for oversight of the 340B program[12] at her hemophilia center and was aware of the potential for abuse. She has participated as a researcher in a clinical trial sponsored by Novo to evaluate NovoSeven® for reducing bleeding during surgery.

39. From 2008 to 2009, Siegel was a Director of Hematology in Clinical Development, Medical & Regulatory Affairs at Novo. Relator's professional experience in the field of hematology also includes service as a Global Clinical Leader in Hematology in the Global Clinical Development department of Bayer Healthcare Pharmaceuticals Inc., as a Director in the Acquired Bleeding department of CSL Behring, as Head of Clinical Development, Catalyst Biosciences, and as Chief of the Thrombosis

[12] Enacted in 1992, 340B requires drug manufacturers to provide outpatient drugs to eligible health care organizations and covered entities at significantly reduced prices. The intent of the program is to allow the covered entities to maintain services and lower medication costs for patients in order to "[s]tretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." Section 340B of the Public Health Service Act, 42 U.S.C. § 256b *et seq.*

and Hemostasis Branch for the Division of Blood Diseases and Resources at the National Heart Lung and Blood Institute at the National Institute of Health. She is currently working as a Medical Director overseeing a surgery clinical trial for patients with congenital hemophilia A with inhibitors at Takeda (previously Shire, Baxalata, and Baxter).

40. **Defendant Novo Nordisk, Inc.** ("Novo" or the "Company") is a global health care company founded 90 years ago in Denmark. Novo specializes in diabetes care, hemophilia care, growth hormone therapy, and hormone replacement therapy. The Company is headquartered in Denmark, employs approximately 36,300 employees in 75 countries, and markets its products in more than 180 countries.

41. Novo's United States operations are incorporated in the state of Delaware under the name Novo Nordisk, Inc. Novo's registered agent is The Corporation Trust Company, located at 1209 Orange Street, Wilmington, Delaware 19801.

42. Novo's United States operations are headquartered in New Jersey at 800 Scudders Mill Road, Plainsboro, New Jersey 08536. The Company has United States production and R&D facilities located in Clayton, North Carolina and Seattle, Washington, respectively. Moreover, according to the Company's website, Novo has sales representatives "in communities in nearly every region of the country."[13]

43. Defendant has frequently flaunted laws governing the marketing of its products where payment is made by government payors. It has paid tens of millions of

[13] http://www.novonordisk-us.com/documents/content_pages/branding_page/1_3_Locations.asp

dollars in settlements with federal and state governments.[14] Novo seems to believe that the monies paid were nothing more than the cost of doing business, a fee for the license to break the law. Indeed, between 2011 and 2016, Defendant was bound by a government-imposed CIA.[15] Notwithstanding the misconduct alleged in this Consolidated Complaint, Defendant and its employees – including one of the brand managers for the NovoSeven® product – routinely and falsely certified to the United States that Novo was in compliance with the very laws this Consolidated Complaint alleges were broken.

IV. STATUTORY AND REGULATORY PROVISIONS APPLICABLE TO DEFENDANT NOVO'S FALSE CLAIMS VIOLATIONS

A. GOVERNMENT HEALTH PROGRAMS

44. The federal and state governments, through their Medicare and Medicaid programs, are among the principal payers who reimburse patients for Novo's pharmaceutical products. Medicare is a federal government health program that

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[14] *See* https://www.justice.gov/opa/press-release/file/994746/download ($12.5 million); https://www.justice.gov/opa/pr/novo-nordisk-agrees-pay-58-million-failure-comply-fda-mandated-risk-program ($58.65 million); https://www.justice.gov/opa/pr/danish-pharmaceutical-novo-nordisk-pay-25-million-resolve-allegations-label-promotion ($25 million);

[15] In June 2011, the Department of Justice ("DOJ") reached a settlement with Novo wherein Novo agreed to pay $25 million to resolve allegations of off-label promotion of NovoSeven® for patients who did not have hemophilia including as a coagulatory agent for trauma patients, general surgery, cardiac surgery, liver surgery, liver transplants and intra-cerebral hemorrhage. https://www.justice.gov/opa/pr/danish-pharmaceutical-novo-nordisk-pay-25-million-resolve-allegations-label-promotion. As part of its settlement with the Government, Novo entered into a multi-year CIA, ending in 2016, wherein Novo agreed to, among other things, take numerous remedial steps to ensure compliance with FDA promotional rules and regulations. *Id.* The unlawful conduct alleged herein violates Novo's CIA with the Government and is on-going.

primarily benefits the elderly and the disabled. It was created by Congress in 1965 when it adopted Title XVIII of the Social Security Act. Medicare is administered by the Centers for Medicare and Medicaid Services ("CMS").

45. Medicare Part A covers hospital services. Medicare Part B ("Part B") pays for some services and products that are not covered by Medicare Part A, usually on an outpatient basis, such as cheapy, renal dialysis, outpatient hospital procedures and durable medical equipment. Hemophilia patients on Medicare receiving infusions of factor, including NovoSeven®, are covered by Part B.

46. All Medicare providers certify, *inter alia*, that "payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the supplier's compliance with all applicable conditions of participation in Medicare." CMS Form 855i, Medicare Enrollment Application Physicians and Non-Physician Practitioners (dated 12/18), at 23.[16]

47. Congress created Medicaid at the same time it created Medicare in 1965 by adding Title XIX to the Social Security Act. Medicaid is a public assistance program that provides payment of medical expenses primarily for low-income patients. Funding for Medicaid is shared between the federal and state governments. The federal government also separately matches certain state expenses incurred in administering the Medicaid

[16] Available at http://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/cms855i.pdf.

program. While specific Medicaid coverage guidelines vary from state to state, Medicaid's coverage is generally modeled after Medicare's coverage, except that Medicaid usually provides more expansive coverage than does Medicare. In particular, Medicaid has broad coverage for prescription drugs. Nearly every state has opted to include basic prescription drug coverage in its Medicaid plan. According to CMS, "[w]hen services are furnished through institutions that must be certified for Medicare, the institutional standards must be met for Medicaid as well. In general, the only types of institutions participating solely in Medicaid are (unskilled) Nursing Facilities, Psychiatric Residential Treatment Facilities, and Intermediate Care Facilities for the Mentally Retarded."[17]

48. At present, CMS is instructed not to deny coverage based solely on the absence of FDA-approved labeling if the use is supported in certain medical compendia and not listed as unsupported. However, the guidance is written in the disjunctive and if a use is not safe or effective, as evidenced by peer-reviewed literature, that *alone* provides a basis (and, as a matter of science, an obligation) for a contractor effectuating CMS to deny coverage or reimbursement. Specifically, Chapter 15, section 50.4.5 at D of the Medicare Benefit Policy Manual states:

> If a use is identified as not indicated by the Centers for Medicare and Medicaid Services (CMS) ***or*** the FDA, ***or*** if a use is specifically identified as not indicated in one or more of the compendia listed, ***or*** if the contractor determines, based on peer-reviewed medical literature, that ***a particular use***

[17] *See* http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandComplianc/index.html?redirect=/certificationandcomplianc/02_ascs.asp.

> ***of a drug is not safe and effective,*** the off-label usage is not supported and, therefore, the drug is not covered."

(emphasis added).

49. The Federal Employees Health Benefits Program ("FEHBP") provides health insurance coverage for more than 8 million federal employees, retirees, and dependents. FEHBP is a collection of individual health care plans, including Blue Cross and Blue Shield plans, Government Employees Hospital Association, and Rural Carrier Benefit Plan. FEHBP plans are managed by the U.S. Office of Personnel Management.

B. FDCA AND FDA REGULATIONS

50. Pursuant to the Food, Drug and Cosmetics Act ("FDCA"), 21 U.S.C. §§ 301, *et seq.*, the Food and Drug Administration ("FDA") regulates drugs based on the "intended uses" – also known as "indications" – for such products. Before marketing and selling a prescription drug, a manufacturer must demonstrate to the FDA that the product is safe and effective for *each* indication for which it intends to market the drug. 21 U.S.C. § 355(a). The FDA reviews pharmaceutical manufacturers' applications for new drugs to determine whether the drugs' intended uses are safe and effective. *See* 21 U.S.C. § 355.

1. Off-Label Marketing Violates the FDCA and FDA Regulations

51. Once a drug is approved for a particular indication, doctors are free to prescribe the drug for uses that have not been approved by the FDA – so-called "off label" uses – and may independently request information from drug manufacturers about such uses. However, with very few exceptions, the FDA strictly prohibits drug manufacturers from marketing or promoting drugs off-label for uses that have not

undergone FDA scrutiny and approval (*i.e.*, for "intended uses" that are not approved by the FDA).

52. Sales and marketing presentations, advertisements, promotions, or materials provided to physicians for uses other than those approved by the FDA are forms of off-label marketing, which is proscribed by the FDA with the exception of purely scientific medical information provided by qualified medical professionals. 21 U.S.C. §§ 331(a)-(b), 352(a), (f). Specifically, FDA rules prohibit drug manufacturers from disseminating information that is "not based on adequate and well controlled clinical investigations," is "false and misleading," potentially "poses significant risk to the public," or is influenced by the drug manufacturer, rather than independently developed.[18] Further, the FDA guidance prohibits as false and misleading a manufacturer's "discuss[ion of] a clinical investigation where FDA has previously informed the company that the clinical investigation is not adequate or well controlled."[19]

53. Strong policy reasons exist for such strict regulation of off-label marketing. Off-label promotion bypasses the FDA's strict review and approval process. Off-label promotion also removes the incentive to obtain definitive clinical study data showing the efficacy and safety of a product and, accordingly, the medical necessity for its use.

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[18] Guidance for Industry: Good Reprint Practices for Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices, Dept. of Health and Human Services, FDA, Office of the Commissioner, Office of Policy (January 2009), at pgs. 4-5

[19] *Id.*

54. Thus, the FDA and the Centers for Medicare & Medicaid Services ("CMS") have produced and disseminated numerous guidance documents warning against the dangers of off-label promotion and medically unnecessary and unreasonable uses of drugs. They have similarly produced documents warning that prescriptions induced by kickbacks compromise independent medical judgment, are not reimbursable, and can expose physicians to criminal liability.

55. State and federal governments have pursued numerous False Claims Act cases predicated on violations of the FDCA and Anti-Kickback Statute and have recovered billions of dollars in connection with these cases, further underscoring the materiality of these regulations to payment.

2. Drug Labeling and Advertising That is False, Misleading or Lacks Fair Balance Causes Drugs to be "Misbranded" in Violation of the FDCA and FDA Regulations

56. The FDA strictly regulates the content of direct-to-physician product promotion and drug labeling information used by pharmaceutical companies to market and sell FDA-approved prescription drugs and biologics. FDA interprets "labeling" in its regulations broadly to include any items that are 1) descriptive of a drug; 2) disseminated by the manufacturer or its agents; and 3) intended for use by medical personnel. 21 C.F.R. § 202.1(l)(2). Labeling includes, *inter alia*, brochures, booklets, detailing pieces, literature, reprints, sound recordings, and audio-visual material. 21 C.F.R. § 202.1(l)(2).

57. The FDA regulations deem "advertising" to include media-based activities that appear in magazines, newspapers, and professional journals and on television, radio, and telephone communications systems. 21 C.F.R. § 202.1(l)(1).

58. The FDCA defines "misbranding" as the inclusion of misleading statements or the failure to reveal material facts in product labeling or advertising. 21 U.S.C. § 321(n). Any failure by a drug manufacturer to fairly and accurately represent the approved uses, safety and other required information about a prescription drug is considered misbranding and is, as a matter of law, a false and fraudulent statement. 21 U.S.C. §§ 331(a)-(b), 352(a), (f), (n); 21 C.F.R. § 202.1(e)(6), (e)(7), 21 C.F.R. § 1.21.

59. In addition, a drug manufacturer's oral statements and materials presented at industry-supported activities, including lectures and teleconferences, provide evidence of a product's "intended use." If these statements or materials promote a use inconsistent with the product's FDA-approved labeling, it is misbranded because it fails to provide adequate directions for all intended uses. 21 C.F.R. § 99.405.

60. Misbranding may exist where a drug manufacturer's statements, presentations or promotional and marketing materials for an FDA-approved drug, *inter alia*:

a. Expressly or implicitly promote uses, dosages, or combination usage of the drug that is not contained in the FDA approved labeling (*i.e.*, off-label uses);

b. Fail to reveal material facts with respect to consequences that may result from the use of the drug as recommended or suggested in the advertisement;

c. Contain representations or suggestions, not approved or permitted in the labeling, that the drug is better, more effective, useful in a broader range of conditions or patients, safer, or has fewer, or less incidence of, or less serious side effects or contraindications than demonstrated by substantial evidence or substantial clinical experience;

d. Minimize, understate, or misrepresent the side effects, contraindications and/or effectiveness of the drug;

e. Use data favorable to a drug derived from patients treated with dosages different from those recommended in approved labeling;

f. Represent or suggest that drug dosages properly recommended for use in the treatment of certain classes of patients or disease conditions are safe and effective for the treatment of other classes of patients or disease conditions when such is not the case;

g. Contain favorable information or conclusions from a study that is inadequate in design, scope, or conduct to furnish significant support for such information or conclusions; or

h. Suggest scientific validity and rigor for data from studies the design or protocol of which are not amenable to formal statistical evaluations.

See 21 C.F.R. § 202.1(e)(4), (5), (6), and (7).

C. THE FRAUD & ABUSE/ANTI-KICKBACK STATUTES

61. The Medicare-Medicaid Anti-Fraud and Abuse Amendments, known as the Medicare Anti-Kickback Statute (the "Anti-Kickback Statute"), 42 U.S.C. § 1320a-7b(b), which also applies to state Medicaid programs, makes it illegal for an individual knowingly and willfully to offer or pay remuneration in cash or in kind in return for purchasing, ordering, or arranging for or recommending purchasing any good or service that is reimbursed by a federal health care program. *See* 42 U.S.C. § 1320a-7b(b)(2). In accordance with the Anti-Kickback Statute, Medicare regulations also prohibit providers from receiving remuneration paid with the intent to induce referrals or business orders, including the prescription of pharmaceuticals paid as a result of the volume or value of any referrals or business generated. *See* 42 C.F.R. § 1001.952(f). "Remuneration" is broadly defined to include anything of value (including any kickback, bribe, or rebate)

paid directly or indirectly, overtly or covertly, in return for purchasing, ordering, or recommending the purchase or order of any item that is reimbursable. *Id.*

62. The Balanced Budget Act of 1997 amended the Medicare Anti-Kickback Statute to include administrative civil penalties of up to $50,000 for each act violating the Anti-Kickback Statute, as well as an assessment of not more than three times the amount of remuneration offered, paid, solicited, or received, without regard to whether a portion of that amount was offered, paid, or received for a lawful purpose. *See* 42 U.S.C. § 1320a-7a(a)(10).

63. The purpose of the Anti-Kickback Statute is to ensure proper medical treatment and referrals and to limit unnecessary treatment, services, or goods that are based not on the needs of the patient but on improper incentives given to others, thereby limiting the patient's right to choose proper medical care and services.

64. Paying kickbacks taints an entire prescription, regardless of the medical necessity and/or the propriety of its use. The kickback inherently interferes with the doctor-patient relationship and creates a conflict of interest, potentially putting the patient's health at risk.

65. The Anti-Kickback Statute contains statutory exceptions and certain regulatory "safe harbors" that exclude certain types of conduct from the reach of the statute. *See* 42 U.S.C. § 1320a-7b(b)(3). However, none of the statutory exceptions or regulatory safe harbors protect the Defendant's conduct in this case.

66. In 2003, the HHS OIG issued its "Compliance Program Guidance for Pharmaceutical Manufacturers" (the "2003 Guidance"), which explained that "practices

that may be common or longstanding in other businesses are not necessarily acceptable or lawful when soliciting federal health care program business," and that such practices would be illegal if "any *one* purpose of the remuneration [is] to induce or reward the referral or recommendation of business payable in whole or in part by a federal health care program. Importantly, a lawful purpose will not legitimize a payment that also has an unlawful purpose." *Id.* at 13, 14 (emphasis in original). The 2003 Guidance then identified several questions that should be asked to determine if a practice violates the Anti-Kickback Statute, including:

- Does the arrangement or practice have a potential to interfere with, or skew, clinical decision-making?
- Does it have a potential to undermine the clinical integrity of a formulary process?
- Does the arrangement or practice have a potential to increase costs to the federal health care programs, beneficiaries, or enrollees?
- Does the arrangement or practice have a potential to increase the risk of overutilization or inappropriate utilization?
- Does the arrangement or practice raise patient safety or quality of care concerns?

Id. at 1.

67. As set forth in this Consolidated Complaint, the answer to each of these questions with respect to Novo's marketing of NovoSeven® is "Yes."

68. In 2010, the Patient Protection and Affordable Care Act ("PPACA"), Public Law No. 111-148, Sec. 6402(g), amended the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), to specifically allow violations of its "anti-kickback" provisions to be enforced under the False Claims Act, discussed next. The PPACA also amended the statute's

"intent requirement" to make clear that violations of the anti-kickback provisions, like violations of the False Claims Act, may occur even if an individual does "not have actual knowledge" or "specific intent to commit a violation." *Id.* at Sec. 6402(h).

69. The State of Washington also has an anti-kickback statute that is identical to the federal Anti-Kickback Statute. RCW 74.09.240(2) makes it illegal for any person, including any corporation to "offer[] or pay[] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person (a) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made, in whole or in part, under this chapter, or (b) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any goods, facility, service, or item for which payment may be made in whole or in part under this chapter . . . ."

70. As detailed below, Novo repeatedly violated provisions of the Anti-Kickback Statute and Washington State's anti-kickback statute by providing money, free trips, and other incentives to both physicians, patients, and others to induce prescriptions of NovoSeven® that otherwise would not have been written. In turn, many of those prescriptions were paid for by Medicare, Medicaid, and other government-funded health insurance programs.

D. BENEFICIARY INDUCEMENT CIVIL MONETARY PENALTIES

71. Title 42 U.S.C. § 1320a-7a(a)(5), a part of the Anti-Kickback Statute known as the "Beneficiary Inducement CMP" or "CMP," makes it a violation to offer remuneration to a beneficiary of government benefits. Specifically, it prohibits

> [o]ffer[s] to or transfer[s of] remuneration to any individual eligible for [Medicare or Medicaid] that [the offeror] knows or should know is likely to influence such individual to order or receive from a particular provider, practitioner, or supplier any item or service for which payment may be made, in whole or in part, under [Medicare or Medicaid].

(emphasis added).

72. "Remuneration" is defined as "includ[ing] . . . transfers of items or services for free or for other than fair market value," subject to certain exceptions. 42 U.S.C. § 1320a-7a(i)(6).

73. The CMP does not generally apply to drug manufacturers providing remuneration to Medicare or Medicaid beneficiaries because they are not considered to be "providers, practitioners, or suppliers." However, the CMP may apply where a drug manufacturer also owns or operates, directly or indirectly, pharmacies, pharmacy benefits management companies, or other entities that file claims for payment under the Medicare or Medicaid programs.

74. Entities that violate the CMP are liable for significant civil penalties, namely

> a civil money penalty of not more than $ 20,000 for each item or service . . . . In addition, such a person shall be subject to an assessment of not more than 3 times the amount claimed for each such item or service in lieu of damages sustained by the United States or a State agency because of such claim . . . .

42 USCS § 1320a-7a(a).

E. THE FALSE CLAIMS ACTS

75. The Federal False Claims Act and the Washington Medicaid False Claims Act (modeled on the federal false claims act) provides that any person who (1) knowingly

presents or causes another to present a false or fraudulent claim for payment or approval, or (2) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim is liable for a civil penalty of not less than $10,781 and not more than $21,562 for each such claim, plus three times the amount of the damages sustained by the government. 31 U.S.C. § 3729(a)(1)(A) & (a)(1)(B), 28 C.F.R. § 85.3. Twenty-two states and the District of Columbia have also enacted False Claims Act statutes that apply to Medicaid fraud.

76. The Washington Fraudulent Practices Act provides that, " No person, firm, corporation, . . . or other legal entity . . . shall, on behalf of himself or herself or others, obtain or attempt to obtain benefits or payments under this chapter in a greater amount than that to which entitled by means of: (a) A willful false statement; (b); By willful misrepresentation or by concealment of any material facts; or (c) By other fraudulent scheme or device . . . ." RCW 74.09.210(1). RCW 74.09.210(2) further provides that, "Any person or entity knowingly violating any of the provisions of subsection (1) of this section shall be liable for repayment of any excess benefits or payments received, plus interest at the rate and in the manner provided in RCW 43.20B.695. Such person or other entity shall further, in addition to any other penalties provided by law, be subject to civil penalties. The director or the attorney general may assess civil penalties in an amount not to exceed three times the amount of such excess benefits or payments . . . ."

F. THE CALIFORNIA INSURANCE FRAUDS PREVENTION ACT

77. The California Insurance Frauds Prevention Act prohibits the knowing employment of "runners, cappers, steerers or other persons to procure clients or patients

... to perform or obtain services or benefits under a contract of insurance or that will be the basis for a claim against an insured individual or his or her insurer." Cal. Ins. Code § 1871.7(a). It also establishes liability for parties that violate "Section 549, 550, or 551 of the Penal Code...." Cal. Ins. Code § 1871.7(b).

78. California Penal Code § 549 makes it illegal for any firm or corporation to "solicit[], accept[],or refer[] any business to or from any individual or entity with the knowledge that, or with reckless disregard for whether" that individual or entity will present or cause to be presented any false or fraudulent claim for payment of a health care benefit.

79. California Penal Code § 550 makes it illegal for any firm or corporation to "[k]nowingly present or cause to be presented any false or fraudulent claim for the payment of a loss or injury, including payment of a loss or injury under a contract of insurance"; "[k]nowingly prepare, make, or subscribe any writing, with the intent to present or use it, or to allow it to be presented, in support of any false or fraudulent claim"; or "[k]nowingly make or cause to be made any false or fraudulent claim for payment of a health care benefit." Cal. Penal Code §§ 550 (a)(1), (5), and (6).

80. California Penal Code § 550 also makes it illegal for any firm or corporation knowingly to present, or to assist or conspire to

> [p]resent or cause to be presented any written or oral statement as part of, or in support of or opposition to, a claim for payment or other benefit pursuant to an insurance policy, knowing that the statement contains any false or misleading information concerning any material fact . . . [and to] [p]repare or make any written or oral statement that is intended to be presented to any insurer or any insurance claimant in connection with, or in support of or opposition to, any claim or payment or other benefit pursuant to an

> insurance policy, knowing that the statement contains any false or misleading information concerning any material fact.

Cal. Penal Code §§ 550 (b)(1), (2).

81. The legislative findings and declarations associated with the California Insurance Frauds Prevention Act make clear that the legislature was concerned with health care fraud:

> Health insurance fraud is a particular problem for health insurance policyholders. Although there are no precise figures, it is believed that fraudulent activities account for billions of dollars annually in added health care costs nationally. Health care fraud causes losses in premium dollars and increases health care costs unnecessarily.

Cal. Ins. Code § 1871(h).

V. BACKGROUND INFORMATION ON HEMOPHILIA

82. Hemophilia refers to a family of inherited and acquired bleeding disorders where those affected lack certain proteins in their blood – called "factors" – necessary to clot off a bleed. Without one of these factors, patients with hemophilia can bleed uncontrollably from injuries that would naturally stop bleeding and heal over in a healthy person.

83. Hemophilia A and B are congenital and affect primarily males. It is estimated that about 1 in 10,000 people have hemophilia A or B or about 20,000 people in the U.S. in 2011.

84. Patients with hemophilia A have either no, decreased, or defective production of the blood clotting protein factor VIII ("FVIII"). Those with hemophilia B have similar impairments with factor IX ("FIX"). Hemophilia is categorized as "mild,"

"moderate," or "severe" depending on the activity of the affected clotting factor (FVIII or FIX) as a percentage of normal. Severe hemophilia is often associated with spontaneous bleeding (*i.e.*, bleeding in the absence of evident trauma or injury). Approximately 7 out of 10 hemophiliacs are categorized as "severe" and can require treatment to stop spontaneous bleeding several times per month.

85. Severe hemophilia usually becomes apparent in the first years of life – often when a child starts to move about independently. Hemorrhages often occur in the joints (particularly weight-bearing joints, such as knees and ankles). These joint bleeds can cause severe pain and often cause permanent damage and disability. Other mild, moderate or even life-or-limb threatening bleeds can occur in muscles, soft tissues, gastrointestinal tract, or even the brain. In addition, trauma, major surgery, and even tooth extractions and other minor surgical procedures require medical treatment to manage the associated bleeding.

86. Hemophilia is treated by intravenous administration of the deficient factor. Patients with Hemophilia A and B are normally treated with FVIII and FIX, respectively.

87. Over time, patients with hemophilia A or B may develop inhibitors to FVIII or FIX, which are antibodies that inactivate the infused factor. There is only a small group of such patients – approximately 1,500 congenital PHIs in the United States.

88. A patient that develops these inhibitors does not respond as well or at all to a FVIII or FIX infusion. When this occurs, patients may respond to one or both of only two bypassing agents on the market: NovoSeven® and FEIBA.[20]

89. Children with hemophilia can develop joint and other musculoskeletal problems later in life due to bleeding into joints while they are still young and growing. Therefore, depending on the severity of the hemophilia, children may be prescribed a clotting agent for primary prophylactic use – meaning regularly timed doses over an indefinite period of time unrelated to bleeding episodes – to prevent the development of even a first joint bleed.

90. While prophylactic use of clotting factor can be used to try to decrease the rate of spontaneous bleeding events for some adult patients with hemophilia without inhibitors (i.e., patients who are not taking FEIBA or NovoSeven®), a 2012 article in the journal Blood Transfusion explains that "the case for prophylaxis in adults remains open to debate and perhaps the true answer is that there actually is no answer, because we have no evidence-based instruments to ascertain to what extent adults benefit from ongoing prophylaxis."[21]

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[20] In 2017, the FDA approved another medication for patients with inhibitors called Hemlibra, which is manufactured by Genentech, Inc. *See* https://www.fda.gov/news-events/press-announcements/fda-approves-new-treatment-prevent-bleeding-certain-patients-hemophilia. Hemlibra was not on the market during the time relevant to the AC's allegations regarding the Battle of the Brands.

[21] M Franchini and PM Mannucci, *Prophylaxis for adults with haemophilia: towards a personalised approach?*, BLOOD TRANSFUS, Apr. 2012; 10(2): 123-124. Similarly, at the 55th American Society of Hemophilia Annual Meeting in January 2013, after presenting a review of current, evidence-based treatment approaches in hemophilia and continuing unmet needs, Dr. Neil Josephson was quoted by the medical website

VI. SPECIFIC ALLEGATIONS OF NOVO'S FALSE CLAIMS

A. IN COMPETING AGAINST FEIBA, NOVO MADE CLAIMS ABOUT NOVOSEVEN® THAT WERE NOT SUPPORTABLE

91. NovoSeven® is a biosynthetic FVII agent indicated for the treatment of acute bleeding episodes in hemophilia A or B patients with inhibitors to FVIII or FIX. It is also approved for the reduction of bleeding during surgical procedures in these same patients.

92. NovoSeven® currently has no medical indications from the FDA for prophylactic use in children or adults or for "high dose" regimens.

93. As alleged in Section I of this Consolidated Complaint, Novo failed to receive prophylaxis and high-dose indications from the FDA because no adequate controlled studies demonstrated that NovoSeven® is, in fact, safe and effective for these uses.

94. By early 2007, the FDA had rejected Novo's submission of the 1505 study (*i.e.*, the Konkle Study), a small trial of 22 patients, to support a prophylaxis indication. Instead, the FDA required Novo to establish the effectiveness of daily prophylaxis through a more robust Phase III trial that was both randomized and controlled. The FDA approved a Phase III study that would evaluate three dose levels for prophylaxis (20, 50, and 90 μg/kg), to establish an unbiased assessment of both minimum dose level as well as

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Medscape.com as stating, "One issue for adults is that there are no 'iron-clad' data similar to those from the Joint Outcome Study or ESPRIT to demonstrate that a patient is going to have a better outcome on prophylaxis."

the efficacy of prophylactic use. This information was never provided to physicians or even to Relator.

95. Internal documents explain that the company opted not to pursue the Phase III study the FDA required for a prophylaxis indication for several reasons. Among other things, (1) the guaranteed loss of revenue that would occur in the short run (due to the fact that patients put in the study – many of whom were already paying NovoSeven® patients – would be given free drugs by the company, creating lost sales) outweighed the potential long-term revenue gain; (2) NovoSeven® "may not be the ideal product for prophylaxis"; and (3) there was a "'low' likelihood of [positi]ve results." Further, the company feared that the study proposed by FDA would establish efficacy of NovoSeven® at a lower dose than the 90 μg/kg recommended in the package insert. If lower doses were found to be effective, Novo's sales would drop: a "[l]ow dose would [] be contradictory to [Novo's] global path and create[] a negative business case."

96. In addition, in 2009 there was concern that the Phase III study would not replicate the results of the Konkle study, which had shown that prophylaxis resulted in a bleed reduction rate of approximately 45-59%. Results from a then-ongoing real-world study (ProPACT) suggested that prophylaxis with NovoSeven® might result in only a 40-50% bleed reduction, which was substantially lower than doctors expected and likely lower than FEIBA prophylaxis could achieve.

97. With respect to the high-dose indication, in August 2007, the FDA denied Novo's application for a label change approving single, high doses of 270 μg/kg. Whether to seek to do another trial to support the 270-μg label change was the subject of

numerous Novo emails and analyses. Specifically, Novo management wanted to know what label change should be sought that "would allow for promotion of 270 μg/kg dosing regimen, while at the same time have the lowest regulatory bar and thereby, the 'simplest' trial requirements."

98. Management also wanted to know what a less-rigorous Phase II study would require because such studies, although not sufficient for FDA approval, could be published and used for marketing the high dose.

99. The result of these analyses was that a Phase III study "to achieve label update" was not recommended. Instead, a Phase II trial was recommended "to generate publication." The determination not to pursue the actual label update was based, in part, on the fact that other studies Novo had performed indicated that bleeds for most patients were controlled with just two 90 μg/kg doses, in which case, "how c[ould Novo] justify a single dose of 270 μg/kg."

100. In 2008, Relator designed a study to determine whether increasing the size of single doses of NovoSeven® (*i.e.*, high doses) would result in safe and more effective control of acute joint bleeds in hemophilia patients with an inhibitor. This study would have evaluated the effectiveness of higher doses of NovoSeven® in controlling joint bleeding. It was designed to differentiate dose requirements based on the specific joint and whether or not the joint was already damaged (*i.e.*, arthropathy) and/or was considered to be a "target" joint (a joint likely to bleed in a particular patient). The study would have provided an individualized assessment for each patient enrolled. The company aborted the study when it learned that the study was designed to actually

determine the correct dosing through a step-wise dosing design rather than to demonstrate the need for high-dose treatment for all patients. Believing that the outcome might actually reduce the dose currently being prescribed for some or all patients, Novo managers instructed Relator and others not to proceed.

101. In short, Novo had no interest in learning how to use NovoSeven® more effectively, if that might lower revenue for the drug. Novo determined not to pursue additional indications because the resulting science would likely interfere with its marketing efforts to sell NovoSeven® for prophylaxis and high doses.

102. In addition to its lack of indication for prophylaxis and high-dose regimens, Novo was aware that its product was perceived to have potential deficiencies that Baxter's FEIBA did not share. An internal Novo business plan from 2008 admits the "weaknesses" of NovoSeven® to be, *inter alia*, (1) its short half-life (the amount of time that the medicine remains active in the body before it is half gone) of approximately three hours; (2) perceived lack of efficacy in relation to Factor VIII products that were indicated for prophylaxis; (3) high price; and (4) lack of U.S.-based clinical trials.

103. FEIBA, on the other hand, is cheaper and has a much longer half-life. It is an Anti-Inhibitor Coagulant Complex FDA-approved for use in hemophilia A and B patients with inhibitors for: (1) control and prevention of bleeding episodes; (2) perioperative management; and (3) routine prophylaxis to prevent or reduce the frequency of bleeding episodes. Thus, unlike NovoSeven®, FEIBA has an indication for prophylaxis in both children and adults. Even Novo admitted the advantages of FEIBA in its business plans, where it noted the "[s]uccess of FEIBA prophylaxis treatment" and

stated that FEIBA "is quite efficacious in most cases leading to a percentage of patients following this protocol long term."

104. Notably, however, with only two bypassing agents on the market to treat PHIs and only 1,500 congenital PHIs in the United States, Novo and Baxter have fiercely competed against each other for every single patient. Novo has dubbed its competition with Baxter the "Battle of the Brands." As Novo's internal documents make clear, the only way it could increase its sales of NovoSeven® was by either converting patients who are taking FEIBA, thereby increasing the number of patients who use NovoSeven®, or promoting off-label uses (for prophylaxis or in high doses) to doctors and patients, thereby increasing the amount of NovoSeven® used by a patient. An internal Novo memo explains, "Value per patient is approximately three times larger for prophylaxis usage than for other indications." Another Novo analysis showed that a congenital PHI on prophylaxis was worth on average $2 million per year in comparison to $670,000 for using NovoSeven® only on demand for acute bleeds. The average cost per treatment was $35,000 for a congenital PHI's on-demand use, while it was $227,000 for prophylaxis.

105. Defendant not only promoted its product for unapproved uses; it tracked the revenue from its illegal efforts. An internal Novo document reveals that by March 2012, 15% of NovoSeven®'s revenue stream -- or $109 million -- was for off-label uses. The document also indicates that $453 million in NovoSeven® sales is attributable to use by congenital PHIs. Relator believes that the majority of that segment of sales was also attributable to prophylaxis and high dose.

106. Utilization of NovoSeven® was often concentrated in a limited group of prescribers, hospitals and patients. In 2012, outlier patients (64 of them) each used an average of $3.6 million of NovoSeven® per year, which represented 51% of sales in Hemophilia Treatment Centers. Not only did the Defendant track off-label usage but it was able to target its marketing efforts on a granular patient-by-patient basis in order to drive the off-label – and dangerous – usage.

107. Defendant's lobbying of individual patients was unmerciful and dangerous. In one case involving a Washington State Medicaid patient, Defendant's one-on-one patient lobby efforts resulted in the patient – a minor – being pumped with tens of millions of dollars of NovoSeven® for unapproved and dangerous uses which were paid for with Washington state and federal Medicaid dollars. For example, in just the five year span between 2009 and 2013, Washington paid $53,042,060.19 in claims for this patient's usage of NovoSeven.

108. To induce this individual patient and his guardian, Novo plied the patient and his guardian with money and in-kind donations including tutoring lessons, travel and meal expenses, computer programming, a computer, and a wheelchair lift. Putting on a full court press, three Novo sales representatives at a time plied the patient and his family with dinners. When the patient's doctor was resistant to using NovoSeven® for prophylaxis, Novo brought in one of its paid KOL's to promote NovoSeven® at a talk given at the patient's medical facility. Through its unlawful conduct, Novo developed such a close relationship with the patient and his guardian that it turned the guardian over

to an ad agency for further illegal promotion of NovoSeven®. Meanwhile, the patient was seemingly sustaining injury from the over-use of NovoSeven®.

109. The motivations were clear. Ignoring the health and well-being of the patients at issue, particularly with regard to a treatment that can cause death, Defendant encouraged its sales force not to think about patient safety at all. On March 30, 2009, Novo Marketing Director Tanya Hill transmitted an email to key members of the NovoSeven® sales force bearing the subject line "Get ready for the Battle of the Brands – April 6th, 2009, Prophylaxis War Game Strategy Meeting." Defendant was fully committed to disrupting the stable medical regimens of those patients using FEIBA for prophylaxis by switching them to a product that was unapproved for prophylaxis or dangerous dosing levels. And to ensure the participation of its sales representatives, Novo made the illegal conduct into a game with performance bonuses for the winners.

B. NOVO CAUSED FALSE CLAIMS TO BE SUBMITTED FOR NOVOSEVEN® VIA SEVERAL SCHEMES

1. Novo Induced Patients to use NovoSeven® Through Kickbacks

110. Early on, Novo realized that because of the small population of PHIs, direct marketing to them was key to expanding the use of NovoSeven®: "The patient is a key decision maker when it comes to treatment selection. It is essential that our patients understand NovoSeven RT and can speak to their [health care provider] regarding treatment with messaging that will resonate with them."

111. As Novo was well aware patients can be unfairly influenced by gifts. Indeed, Novo created internal compliance policies to address such influence – which it

failed to follow. Rather, Novo tracked individual patients and their doctors, engaged in one-on-one marketing to them, and showered them and their caretakers with gifts and benefits in violation of both the Anti-Kickback Statute and the Beneficiary Inducement CMP.

112. Novo created SevenSECURE, a purported "patient assistance program." SevenSECURE was a means of obtaining patient-specific information to be used in marketing Novo's products to them. Patients who signed up had to agree as follows:

> I agree to participate in Seven[SECURE]. I agree that the information I am providing may be used by Novo Nordisk, its affiliates or vendors to keep me informed about new products, services, special offers, or other opportunities that may be of interest to me, as they become available. ***THESE COMMUNICATIONS MAY CONTAIN MATERIAL MARKETING OR ADVERTISING NOVO NORDISK PRODUCTS, GOODS OR SERVICES.***

113. In exchange, patients could apply for and receive various grants to purchase computers and software, for tutoring and lessons for children, or to help with college tuition. *See, e.g.*,

https://www.collegescholarships.com/scholarships/detail/131956?/scholarships/detail/131956 (tutoring and lessons for children);

http://www.hemophiliaprince.com/scholarships.html (noting that under SevenSECURE program, "Adults with inhibitors can apply for grants up to $2500 for training to help improve their career or transition to a new one.");

https://www.collegescholarships.com/scholarships/detail/131956?/scholarships/detail/131956 (same). Patients on the SevenSECURE program could also get Novo-funded credit

cards to use for "medical expenses," but Novo and its agents did not always track purchases to monitor or enforce this requirement.

114. Novo hired a division of Omnicare called RxCrossroads[22] to administer the SevenSECURE program for it. RxCrossroads is nominally a specialty pharmacy – meaning it supplies patients or their doctors with certain types of prescription medications. But it performs a number of other functions for the pharmaceutical companies that hire it, including providing valuable data about the patients it serves to the companies, running logistics and day-to-day management of company-sponsored patient loyalty and co-pay programs, and "[d]eliver[ing] [the companies'] brand message to patients and specialty pharmacies through channels like email, behavioral call campaigns and more." *See* https://www.mckesson.com/about-mckesson/our-company/businesses/rxcrossroads/. As the RxCrossroads website explains:

> Our comprehensive suite of solutions for biopharma and life sciences companies will help you create, execute and measure the performance of a customized brand strategy across every stage of your product's lifecycle.

Id.

115. In short, RxCrossroads is a multi-functional promotional entity that pharmaceutical companies retain to provide logistics and improve their revenues. Of prime importance, RxCrossroads became the conduit for patients to receive remuneration, including grants to buy computers, pre-paid credit cards to be used ostensibly only for medical expenses, and co-pay assistance. Moreover, as a pharmacy itself, RxCrossroads

[22] At the time, RxCrossroads was a subdivision of Omnicare, Inc. It has since been acquired by McKesson.

was receiving kickbacks from Novo as an inducement for it to move patients to NovoSeven®.

116. SevenSECURE and/or its affiliate programs also provided free drugs to certain patients who did not have insurance coverage. However, this practice – which is known as "seeding" – was not for all such patients. It was only for patients who were expected to eventually gain coverage and be able to pay for the drug. The goal was to capture patients early, since Novo knows that most patients will continue a treatment once it is begun, all things being equal. On more than one occasion, Novo sales representatives sought exceptions to this rule from Novo management for patients who had been denied free drugs because they did not intend to obtain any kind of coverage in the future. The exception was not requested for the benefit of the patient, but for the benefit of the sales representatives. As one representative explained, he was concerned that the treating facility, Henry Ford, would turn instead to Baxter. The representative explained that

> It will really help as Henry Ford said they're going to check with Baxter and if we can make an exception it will really help and especially in light of the fact that we've lost Angie Lambing [a health care provider] at Henry Ford.

117. In addition to having RxCrossroads promote SevenSECURE, Novo hired Cline Davis & Mann, an advertising company, to develop a promotion strategy. The agreement provided that one approach would be to feature patients such as PATIENT A, a patient who used large amounts of NovoSeven® for prophylaxis, as "ambassadors" in emails recommending that patients sign up with SevenSECURE. A storyboard created

by Cline Davis & Mann features PATIENT A and his parent discussing all of the "support" they received from SevenSECURE, which included Novo grants for a computer, a Rosetta Stone software class, and a wheelchair lift for PATIENT A's parent to use. The storyboard also noted that PATIENT A was applying for a Novo grant to help pay for college. Thus, the message was not that SevenSECURE provided patients with medical assistance, but rather that it provided them with lucre of varying sorts. All of the emoluments provided to patients under the SevenSECURE program constituted kickbacks that violated the Anti-Kickback Statute, Washington Anti-Kickback Statute and Beneficiary Inducement CMP.

118. Novo was well aware that SevenSECURE and affiliated programs did not comply with these statutes. Internal emails show that as late as 2014, Novo employees were aware that Medicare and Medicaid patients received assistance through the program. It wasn't until 2015 that they changed the rules to prohibit patients with government insurance from participating in SevenSECURE.

119. Novo tasked RxCrossroads to administer SevenSECURE, which involved giving targeted PHIs gifts, free drug where there was a possibility that a third-party payor would step in and make payments, and assistance by pulling through the payment, *inter alia*, using Novo sponsored journal articles (lacking any rigorous study data) to secure reimbursement from third-party payors. Curiously, the Novo/RxCrossroads contract was reviewed by an outside Omnicare business lawyer who cleared it despite acknowledging that no safe-harbor exemptions from the Anti-Kickback Statute applied. Yet, the contract on its face implicated conduct violative of federal law, and the two parties to it – Novo

and RxCrossroads – were two entities that had been held liable for violating the Anti-Kickback Statute for the very conduct called for by the contract.

120. The monies paid to RxCrossroads by Defendant, including the monies deposited into accounts and placed on the credit cards of target PHIs, was done with intricate coordination. Defendant's SevenSECURE Brand Manager Stacy O'Donnell had daily email exchanges with her counterpart at RxCrossroads, Luke Hemming. Novo directed and was aware of benefits directed on a patient-by-patient basis. Indeed, O'Donnell often tasked Hemming and his cohorts at RxCrossroads with marketing directly to patients.

121. Notwithstanding a contract that memorializes a conspiracy to break the law and daily micro-management of RxCrossroads' efforts by Stacy O'Donnell, Novo has tried to create the narrative that its relationship with RxCrossroads was more in the form of a contribution to an independent, charitable third party for the benefit of a vulnerable patient population. This was far from the truth. Novo's relationship with RxCrossroads was a contract with a for-profit entity, not a charitable contribution to a non-profit. Moreover, the pharmacy did not function as an "independent third party" who made all the decisions with respect to what gifts and benefits patients would receive. Rather, as explained above, Novo could – and did – make such decisions itself.

122. Further, the Novo/RxCrossroads contract required RxCrossroads to meet certain "Key Performance Indicators" and "Deliverables," including offering at least 90% of the patients it encountered an opportunity to be contacted by Novo sales representative. Failure would result in "[f]inancial penalties." Novo also provided

RxCrossroads with a "Checklist" of what was expected for each patient interaction, including "[i]dentity[ing] which customer needs SevenSECURE® can support" and "[a]ssess[ing] interest [i]n meeting with the local Novo Nordisk Representative." RxCrossroads was also required to provide Novo with information about the patients who received aid through its programs, including emailing sales representatives when new patients signed up for the program in their territories. In particular, Novo tracked approximately 104 "High Dose N7 Users" for fifteen months, from January 2011 to March 2012, including their names, dosing instructions and monthly spend on NovoSeven, physicians' names, and insurance carriers. Significantly, most of these patients were on either Medicare or Medicaid.

123. Novo sales representatives entreated doctors to sign up PHIs to the SevenSECURE program. To guarantee that no marketing money was wasted, doctors had to certify that the enrolled patient had an inhibitor. Once signed, the patient – whether a NovoSeven® user or a FEIBA user – was subject to Novo's marketing ploys. Defendant sought to influence these patients to either keep them on NovoSeven® or convert them from FEIBA.

124. Once a patient was signed to participate in SevenSECURE, RxCrossroads would process the application and alert the relevant Novo sales representative that a particular doctor had enlisted a patient. An internal RxCrossroads checklist confirmed that RxCrossroads would than contact the patient and ask whether the patient would meet with a Novo sales representative.

125. Internal emails between RxCrossroads and Novo confirm that RxCrossroads employees – including Luke Hemming and those supervised by Hemming – promoted to patients on an individual basis to encourage conversion from FEIBA to NovoSeven® or to encourage NovoSeven® users to stay on the product. Hemming and his crew received particular praise from their counterparts at Novo when a patient was converted for prophylaxis treatment – a use of the product that meant an exponential increase in per-patient revenue.

126. Internal emails also confirm that Novo tasked RxCrossroads to cultivate marketers who could reach out to patients and/or their guardians who only spoke Spanish.

127. In all of its outreach, RxCrossroads had at its disposal a host of benefits that it could use to influence patient decision-making. Those benefits included, *inter alia*: (1) providing patients with insurance premium assistance, cost reimbursement for medical or dental care, childcare expenses, and scholarships for higher education degrees or training programs; (2) providing coordination of shipment of product, coordination and execution of timely and accurate product refills, answering patient questions and concerns regarding the proper usage of the product, as well as collecting and reporting adverse drug side effects or reactions to patient physicians and Novo; (3) processing patient enrollment forms and the coordination of sample product shipments to patients who were starting on NovoSeven®.

128. RxCrossroads was also required to provide Novo with monthly reports that detailed who was enrolled, who referred the patients, what benefits patients received, the cost of the grants and other benefits provided to patients, and similar information.

2. Novo Off-Label Marketed NovoSeven® Directly to Patients Through Sponsored Inhibitor Camps and Adult Patient Weekend Retreats and Provided Patients With Other Kickbacks

129. Notwithstanding a 2008 Novo Policy on Interactions with Patients in the Field, which clearly recognizes (and ostensibly prohibits) the potential kickback implications of such interactions, Novo actively marketed NovoSeven® off-label directly to patients and their families for adult and child prophylaxis or to switch from using FEIBA through a number of recurring marketing events designed and paid for by the Company. These events were ostensibly advertised as educational events, including "weekend summits" for adults with hemophilia and inhibitors and "inhibitor camps" for children. These summits and camps were advertised or offered either by Novo directly or through patient advocacy groups and hemophilia vendors operating under the aegis and financial support of Novo. At these events, prophylaxis – among other therapies – was promoted to patients and their families and caregivers.

130. For example, the National Hemophilia Foundation ("NHF") advertised on its website a "2009 Inhibitor Education Summit," which indicated that one of the key topics to be discussed by the speakers was "current management options for patients with hemophilia and inhibitors, such as prophylaxis...." Specifically, the agenda indicated that "Prophylaxis with Bypassing Agents" would be discussed for patients registering for events designated as "Track 1: Hemophilia with Inhibitors 101." The agenda for "Track 3: Young Men – Hemophilia with Inhibitors" was a discussion about "Early Treatment of Bleeding and Prevention of Joint Disease." The terms "early treatment" and

"prevention" were – and still are – used by Novo as promotional terms to enhance their message to self-infuse more often, at higher doses, and as prophylaxis.

131. The Novo label was prominently displayed on the first page of the Inhibitor Education Summit web advertisement, with words indicating that the event was "supported by an educational grant from Novo Nordisk." The Inhibitor Summit appears to have received no support from Novo's competitor Baxter. Indeed, the two Co-Chairs for this particular summit were Dr. Leonard Valentino and Dr. Guy Young, who were both Novo KOLs.

132. In addition to funding the Inhibitor Summit, Novo (with the message delivered by NHF) also attempted to influence patients (and their caregivers) by paying them to attend the event and/or giving them other gifts and benefits. For example, the advertisement indicated that "travel grants are available" for patients and their families covering the cost of travel (including air fare), and on-site lodging. The two events in 2009 were held in Washington, D.C. and Hollywood, California during the summer. Free childcare at these events was also provided. Such perks can be a powerful influence for patients and their families.

133. Notably, internal documents reveal that the camps and summits were staffed largely by Novo sales representatives, who were therefore in close contact with the patients and able to pitch them on off-label uses of NovoSeven®.

134. Novo also recruited charismatic PHIs to help convey its off-label marketing messages at summits and camps for PHIs. For example, the caretaker of PATIENT A, discussed above, was on the Steering Committee of the NHF 2009 Summit. In addition,

an on-line newsletter reporting on the events of a 2007 inhibitor summit in San Diego indicated that PATIENT B, another PHI who used large amounts of NovoSeven®, attended the summit as did Novo KOL Dr. Guy Young and Novo marketing employee Ms. Gar Park.

135. Novo also featured PATIENT B in educational literature disseminated to patients by Novo. PATIENT B discussed his use of NovoSeven® in prophylaxis and was paid by Novo to attend summits for patients and their caregivers to speak on behalf of the Company.

136. While Novo has paid for similar summits and camps since at least 2005, in 2007 Novo transitioned some of its direct-to-patient marketing events, such as the inhibitor camps and summits, to NHF by issuing a sham "Request for Performance." By securing NHF to assist in its marketing, Novo was able to disguise its unlawful marketing tactics.

137. To this day, Novo supports a myriad of all-expense-paid marketing events similar to the Inhibitor Summit described above. For example, Novo was the sole sponsor of an Inhibitor Family Camp, marketed by Comprehensive Health Education Services, L.L.P. ("CHES"), held in the summer of 2012 at the Rocking Horse Ranch Resort Center in New York. Although CHES purports to be an education resource for patients with hemophilia, its website indicates that its two founders are long-time industry advocates.[23] CHES was founded in 2009 by Janet Brewer and Eric Lowe. Ms.

[23] *See* https://ches.education.

Brewer served on Novo's "Consumer Council" from 2009 to 2011, concurrently during her tenure at CHES, and was a past director of educational programing for a "small home health care" company selling clotting factor to patients with hemophilia. CHES's website likewise notes that Mr. Lowe, who suffers from hemophilia with inhibitors, is often "featured as an advocacy resource for companies in the bleeding disorder industry." At the CHES camp, there is no need for patients to apply for a grant because everyone attends free, air fare is arranged, all travel expenses are reimbursed, and all meals are provided.

3. Novo's Off-Label Marketing was Orchestrated at the Highest Levels of the Company

138. Relator Siegel began her tenure with Novo in or about January 2008. Relator's position with the Company was in clinical development. At Novo, like other pharmaceutical companies, the clinical development team or division is primarily responsible for developing clinical trial protocols for new drugs and new uses of existing drugs. Relator learned that while some of her duties at Novo included the development of trials, Novo had hired her primarily to assist in their formulation and implementation of off-label marketing of NovoSeven® for adult and child prophylaxis and for doses that were much higher than directed by the label. This was not explained to Relator in interviews and came as a surprise in her first few weeks and months at the company.

139. Within a few weeks of her hire, on January 18, 2008, Relator was invited to a marketing strategy meeting in Princeton, New Jersey, attended by Novo's Business Section including employees from marketing and medical affairs and a Director of

Marketing from Switzerland. Relator was invited to this strategy meeting as a new member of the organization and for her ideas regarding the development of Novo's overall hemophilia marketing strategy, including discussion of potential new agents. The strategy meeting was to identify areas where Novo could expand the sales of NovoSeven®. At the time, Novo anticipated the failure of the intracranial hemorrhage and trauma studies, which had been designed to support an expanded indication for NovoSeven® to treat post-surgical or traumatic bleeding for patients without hemophilia. Even prior to this meeting, the off-label strategy for this use was determined not to have a significant impact on the "bottom line" because only a few doses were used per patient.

140. The January 18th sales meeting was organized by Paul Huggins, Senior Director of International Marketing at Novo. The meeting included Klaus Davidsen, Howard Levy, Gar Park, Michael Ferrara, Michael LaMotta, and David Cooper, all within business development and marketing or medical affairs for Novo. The primary U.S. medical affairs person at Novo at the meeting was David Cooper, Novo's Director of Medical Affairs. Howard Levy, Cooper's manager, was responsible for clinical development, medical affairs, and regulatory affairs ("CMR"), holding the title of Executive Director of CMR. Though Medical Affairs was ostensibly organized to respond to questions or concerns from treating physicians, it was Novo's *de facto* marketing arm. Dr. Cooper used the post-marketing Phase IV data to generate literature touting NovoSeven®'s off-label uses, including for prophylaxis and high-dose regimens.

141. Further muddying the distinction between the marketing and clinical arms at Novo, Novo's Medical Science Liaisons ("MSLs")[24] (also called Hemophilia Medical Liaisons or "HMLs" by Novo) had responsibilities under *both* the Medical Affairs and Clinical Affairs divisions. For example, Novo used MSLs to assist in recruiting sites for its clinical trials (run by the Clinical Operations arm of the company) and simultaneously to carry out marketing directives from Medical Affairs. Thus, MSLs recruited doctors/hospital sites to participate in the Phase IV collection of data for NovoSeven® overseen by David Cooper.

142. In addition, sales representatives were encouraged to coordinate with the company's MSLs on sales calls with physicians, including by collaborating on "action plans to convert patients" from FEIBA to NovoSeven® and off-label marketing efforts. One business plan encouraged sales representatives to have weekly discussions with MSLs to ensure synergy with the account.

143. New to Novo at the time, Relator Siegel was under the impression that the January 18th meeting was intended to cover areas for new research and trials. It quickly became apparent, however, that the purpose of the meeting was primarily to discuss new marketing strategies for NovoSeven®. This focus on the expansion of NovoSeven® into off-label uses continued for the duration of Relator Siegel's employment and it continues

[24] According to the Medical Liaison Society, "The Medical Science Liaison (MSL) is a specific role within the pharmaceutical, biotechnology, medical device, CRO and other health-care industries. MSLs have advanced scientific training and academic credentials generally consisting of a doctorate degree (Ph.D., PharmD., M.D.) in the life sciences. They concentrate on a specific Therapeutic Area (i.e. Oncology, Cardiology, CNS, Pulmonary, Hematology, Surgery, Women's Health Care, etc) and disease state." *See* https://www.themsls.org/what-is-an-msl/.

today. Relator Siegel was asked during the meeting to suggest new research areas to explore. She later learned that her input on potential new research areas was used, instead, to develop new marketing strategies for NovoSeven®, in particular, prophylaxis.[25]

144. On February 5, 2008, a summary memorandum of the January 18 strategy meeting was distributed to the meeting attendees. The email – with the subject line "Haemophilia Portfolio Strategy Workshop" – noted that the key new marketing opportunities included prophylaxis for adults and children. The attached memorandum contained an entire segment entitled "identify opportunity space," which listed five marketing segments deemed to be the "most lucrative." These marketing segments included prophylaxis for adults without factor inhibitors and children both with and without factor inhibitors. The notes to the "opportunity space" section explained that particular attention was to be given to initiating prophylaxis in children and following through with them to adulthood, "when they start to make [their] own decisions regarding therapy choice[s]."

145. The summary memorandum predicted hemophilia treatment trends, which included dramatic increases in prophylaxis among children and adults. The discussion of treatment trends noted ways to maintain patients on prophylactic treatment regimens by

[25] During this meeting Novo's Paul Huggins used a diagram that showed the "expanded pipeline," for NovoSeven®. It is featured in Novo's 2009 Annual Report and shows Novo's marketing plan. Novo, at that time, had received no new indications for NovoSeven®, such as trauma or intracranial hemorrhage and, instead, had greatly expanded its market through off-label promotion for patients with hemophilia with inhibitors.

reaching out to insurance providers to ensure continued coverage for treatment and managing life-time insurance caps.

146. The memorandum also discussed ways to make prophylactic treatment more attractive to potential patients by developing a long-acting form that required fewer administrations throughout the day. The memorandum also discussed marketing strategies for maintaining patent protection against generics in the prophylactic treatment market, including pulling NovoSeven® off the market once its patent expired and replacing it with a drug labeled NN1731, which was purported to work faster and better but, in fact, failed in clinical trials.

147. While many of the ideas discussed above could have been useful product improvements for Novo, it is important to remember that this was a marketing meeting. Novo was finding new ways to market NovoSeven® and expand into other treatment areas in hemophilia either with new drugs or with NovoSeven®, which was indicated only for acute "on demand" treatments, not prophylaxis. Indeed, the memorandum notes that one of the "challenges" to Novo's marketing strategies was the "increasing regulatory scrutiny (FDA)."

148. In the fall of 2008, Novo became concerned about its inability to successfully recruit doctors and patients to participate in clinical trials on new drugs (including new formulations of NovoSeven®).[26] Relator (along with others) was tasked

[26] One primary reason why doctors and patients were difficult to enlist was because doctors would lose revenue by putting their patients into clinical trials, which require the use of free drugs rather than the chargeable 340B-priced drugs.

to help solve the problem. The company was so desperate to find enrollees for clinical trials that Kate Owen, director of Novo's Clinical Trial Operations, resorted to "gain access from marketing to the list of inhibitor patients and their current clinics" and working backwards to their physicians.[27]

149. At the time, Relator believed MSLs might not have possessed sufficient training to promote the clinical trials and decided to provide a training session to them, which she developed. She believed with appropriate training and insight, the MSLs would be able and willing to help support the clinical research program. Relator learned, however, that Novo had other ideas, including to use the MSLs for marketing NovoSeven®.

150. For example, Relator became aware that the MSLs were using the clinical trials as an access point to those physician offices where promotional efforts were not welcomed. Further, MSLs were relaying inaccurate information about the clinical trials and sometimes steering physicians to the less reliable Phase IV studies – the post-marketing studies.

151. Relator further learned that Dr. Cooper's efforts to recruit physicians to work on post-market studies of NovoSeven® were so successful that physicians did not want to put patients into the clinical trials. As explained in Section VIII, below, this was due in part to the fact that physicians and HTCs could capture 340B profits from the use of NovoSeven® on their patients while simultaneously working on post-market studies,

[27] Notably, Owens' actions underscore that Novo's *marketing* department possessed information identifying all of the patients taking NovoSeven® and their physicians.

but they could not get reimbursement for patients in clinical trials, who received the investigational drug provided by Novo for free.[28] Also Medical Affairs provided numerous perks to physicians such as grant money for studies, advisory committee roles, speaking opportunities, and opportunities for publications in medical journals pertaining to NovoSeven®.

152. During her tenure, Relator was involved in many Novo marketing meetings designed to implement the marketing strategy laid out in the February 5 memorandum,[29] including the "Prophylaxis War Games," a reference to Novo's attempt to capture the PHIs who were using Baxter's FEIBA (a competitor to NovoSeven®) for prophylaxis, which was also off-label until 2014 when the FDA approved FEIBA for prophylaxis for adults and adolescents.

153. The prophylaxis war games and other marketing initiatives, including Novo's PRO-PACT prophylaxis study (which was nothing more than a case-study review of 86 patients), were also discussed in an internal Novo memorandum dated April 2009 that indicates that Novo intended to utilize such "strategic brand plan processes" for two to five years.

154. After the January 18, 2008 meeting, Relator Siegel was invited to attend another Novo marketing meeting in Switzerland, called the "Zurich Task Force Group

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[28] The challenges of lost revenue to the company and to doctors when patients were put on investigational drugs in trials was often discussed by the Company's management, including in 2008.

[29] Relator has a calendar that memorializes many of these meetings.

'Prophylaxis Initiative.'"[30] She inquired why she was included since the meeting seemed to be more a matter for Medical Affairs, which was the responsibility of David Cooper. Relator was at that time working on many projects within clinical development that required attention and oversight. Nonetheless, she was told apologetically by her supervisor, Howard Levy that she needed to attend because of her U.S. hemophilia experience.

155. The reason for her inclusion became evident only when she returned from the meeting in Zurich and received a follow-up call from two Novo physicians who had attended as well; she was told that she was expected to use her relationships to find physicians in the U.S. to author publications for Novo promoting off-label use of NovoSeven®. According to the participants in the meeting in Zurich, such publications would be used to counteract the FDA's rejection of expanded use of NovoSeven® for prophylaxis. Once the FDA denied Novo's requests for prophylaxis and high-dose indications, Novo's marketing efforts were focused on identifying physicians who had used or would use NovoSeven® for prophylaxis and publish the results.

156. The 2008 meeting in Zurich included Novo Medical Affairs representatives from all the relevant countries/regions. At the time, for example, the Novo representative from Spain had already identified an investigator who was willing to have his experience using NovoSeven® for prophylaxis written and published. Repeatedly during this meeting, the focus for this prophylaxis initiative was to identify the "low hanging fruit,"

[30] Relator believes this meeting may have occurred on March 6, 2008, as her calendar from her tenure at Novo states "meeting to discuss prophy [prophylaxis] patients."

namely physicians who were willing to provide case reports for publication promoting the benefits of prophylaxis. After the Zurich meeting and follow-up call with the physicians leading the meeting, Relator Siegel informed Levy that she was not willing to identify and encourage physicians to write articles on prophylactic use of NovoSeven®.

157. After Relator's meeting with Levy, Novo asked Dr. Cooper to carry out this assignment instead, which he did, working with other Novo employees. As discussed further below, Dr. Cooper is a co-author of many off-label NovoSeven® articles published in top hemophilia journals during the time period encompassed by this Consolidated Complaint. These articles continue to be relied upon by the medical community to this day.

158. The "studies" that were discussed at the Zurich meeting in 2008 became the Novo-sponsored Pro-PACT Study on prophylaxis, which was conducted from April 2009 to May 2010 and published in 2012 with Dr. Guy Young, a Novo KOL, as first author. *See* G Young, G Auerswald, V Jimenez-Yuste, T Lambert, M Morfini, E Santagostino and V Blanchette, *PRO-PACT: retrospective observational study on the prophylactic use of recombinant factor VIIa in hemophilia patients with inhibitors*, Thromb Res., Dec. 2012, at 130(6):864-70. Much of the information about the studies – such as the sites that agreed to host the study – is not available on Clinicaltrials.gov; rather there is just a referral to a Novo Nordisk Clinical Trial Call Center in Princeton, New Jersey and a study director, Pedro Pina M.D., at Novo Nordisk Health Care AG. Relator has reviewed training session documents she had on the Pro-PACT Study and found that some sites had declined to participate as likely they were not utilizing NovoSeven® for

prophylaxis. The Pro-PACT Study was not designed to get FDA approval for prophylaxis. Rather, Novo used the Pro-PACT Study as yet another vehicle to promote off-label use of NovoSeven®.

159. Another Novo-sponsored study, the DOSE Study was begun in or around October 2009 to collect information on when and why NovoSeven® was utilized and its impact on the patient's bleeding event and functional status. Sites were likely recruited based on their existing practice of off-label use of NovoSeven®. Like the Pro-PACT Study, the DOSE Study generated numerous articles that were used as marketing pieces for Novo to support the use of high doses and prophylaxis. Many of the resulting studies are listed *infra*, Section VI.B.5.

4. Novo Engaged in Off-Label Marketing and Paid Kickbacks to Physicians Through the HTRS Registry

160. Instead of commissioning legitimate clinical studies to obtain an indication for prophylactic use, Novo found a quick and dirty way to manipulate physician opinions and/or capitalize on physicians' current off-label practices by producing "scholarly" articles on high-dose and prophylactic use of its product through the Hemostasis and Thrombosis Research Society ("HTRS") Registry, a database that collected information from treating physicians on patients with any form of hemophilia. The Registry was sponsored by Novo – via the third party HTRS – to comply with FDA post-marketing data collection requirements for NovoSeven® (i.e., Phase IV study).

161. According to the HTRS website, at the time NovoSeven® was approved for sales,

> the FDA required a system of post-licensure monitoring for adverse events to capture safety and efficacy information on patients treated with NovoSeven®. The HTRS registry became this platform, capturing information on treatment of bleeding episodes and during surgeries in congenital hemophilia, congenital factor VII deficiency, and acquired hemophilia[,] among other things.

162. The information gained from this type of registry does not meet the criteria of an "adequate and well-controlled clinical investigation," as defined by FDA regulation.[31] Specifically, publications that used retrospective data mined from the HTRS database did not have adequate measures to minimize "bias" or use methods of assessment that were "well-defined and reliable."[32] "Isolated case reports, random experience, and reports lacking the details, which permit scientific evaluation" fail to meet the FDA standards for dissemination.[33]

163. Because participation in the HTRS Registry was voluntary, it is impossible to determine whether it captured: (1) all treatment events, (2) all doses rather than just the larger doses, or (3) bleeding events that were treated with only one dose at the FDA-approved level (*i.e.*, 90 μg/kg dose as set forth in the package insert) or even with just rest and elevation.

164. Nonetheless, the Registry morphed into a repository of clinical data on off-label uses from which Novo could cherry pick and produce advertising pieces disguised

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[31] *See* 21 C.F.R. § 314.126.

[32] *Id.* at § 314.126(b)(5) (adequate and well controlled studies have "adequate measures … to minimize bias on the part of the subjects, observers, and analysts of the data").

[33] 21 C.F.R. § 314.126(e).

as scholarly articles advocating widespread off-label use of NovoSeven® for prophylaxis and at higher doses than the FDA had approved.

165. Each physician or treatment center that enrolled in the HTRS Registry was required to enter into an agreement with HTRS on the collection and use of information for the Registry. Per the contract, in exchange for generous financial rewards, any time Novo wished to sponsor a research study, all doctors or treatment centers that wished to participate were obligated to identify "all of [their] patients that are eligible for participation in such [s]tudy" and recruit those patients for participation. The physician or treatment center was then obligated to collect the patient's information for the study and put it into the HTRS Registry website per the study's requirements. The contract specifically stated that while the individual treatment centers were allowed to use the information they collected for their own purposes, including publication, they could only do so with prior written consent from HTRS. HTRS, however, was entitled to use all the data submitted to it for its own purposes, "including, without limitation, publication," without the consent of any of the participating treatment centers or doctors.

166. The financial incentives offered to physicians by Novo through the Registry were generous. First, Novo – as sponsor – provided a $1,500 grant to any new participant to purchase a new computer to use for the Registry. The computer was the property of the participant and came with no restrictions other than adequate hardware to participate in the Registry. Novo then paid each participant a "startup grant" of $1,000. Each participant was also paid for the data collected on patients and submitted to the HTRS Registry. The contract lists a schedule in the back with payment rates for various

data collections, including $100 for each new patient registration and $100 for each "acute bleed form" documenting a bleeding event. Participants were further incentivized with volume bonuses for entering bleed data into the Registry. For every 10 bleeding events entered into the Registry per quarter, the participating treatment center or physician was paid a bonus of $1,000. While the contract states that these payments are "data entry grants" designed to "offset the cost of entering bleed data into the Registry," these payments effectively served as kickbacks for participants to enroll as many patients as possible in the Registry. The contract notes that payments to physicians will continue so long as Novo continues to provide the funding. NovoSeven® was approved by the FDA in 1999, and Novo provided continuous funding to the HTRS Registry until it was closed recently. All of these payments violated the Anti-Kickback Statute.

167. The Registry became a vehicle for the sales force to encourage off-label prescriptions for high dose and prophylaxis by physicians by way of Registry-based publications. Novo therefore worked hard to collect data from HTRS Registry participants. In some instances where a treatment center or physician was slow to input data or otherwise indifferent to participation, Novo provided further remuneration in the form of a paid study coordinator to enter information for them. Novo still awarded the Registry participant bonuses for participation. The Novo sales force and MSLs also offered to have Novo employees "write up" positive reports about patient outcomes on behalf of the physician who had prescribed NovoSeven®.

168. Even before Relator's time at Novo she was aware of the practices described above. When Relator was the Director of the Cardeza Hemophilia Center at

Thomas Jefferson Hospital in Philadelphia, a NovoSeven® sales representative encouraged Relator to enter her patients into the Registry and told Relator if she was too busy to enter the data, Novo would pay for a coordinator to enter the required information. The sales representative also told Relator that she could enjoy the added benefit of having Novo write a "case study" from the data, which could be submitted to a medical journal for publication. Relator refused and, on a subsequent visit, told the representative not to return to her office. As described above, Relator later learned that such marketing tactics were centrally devised by Novo and communicated to all its sales representatives.

169. Drug companies commonly use data required by the FDA to be collected in post-marketing surveillance to market drugs off-label or to tout safety or efficacy characteristics not approved by the FDA. For example, a 2012 article published by an anonymous drug company employee in the British Medical Journal details the efforts of a major drug company to use "observational" data to market drugs through various efforts, including paying or offering valuable remuneration to key opinion leaders to deliver marketing messages not approved by the FDA and publishing articles highlighting such uses.[34] Despite the fact that the Government requests that the data be collected, the use of the data for off-label marketing purposes is unlawful.

[34] Post-Marketing Observational Studies: My Experience in the Drug Industry, BMJ, June 12, 2012.

5. Novo had a Publication Strategy to Off-Label Market Through HTRS Articles, CMEs, and Other Materials

170. Novo sought to do an end-run around the FDA's approval process and to ameliorate the lack of firm data on dosing, safety, and efficacy, through an elaborate publication plan that began as early as 2001 with the publication of *Inhibitor treatment: state of the art*. Shapiro A., Semin Hematol. 2001 Oct;38(4 Suppl 12):26-34. In 2007, Novo had already recommended that its "[p]ublication plan [] include a consensus paper outlining unmet medical need, defining patient population and clinical benefits of rFVIIa in prophylaxis."). That consensus paper finally issued in 2013, when the MASAC consensus guidelines recommended "that prophylaxis with bypassing agents [i.e., NovoSeven and FEIBA] should be considered in patients with inhibitors." In making this recommendation, the guidelines relied on two FEIBA prophylaxis studies and one NovoSeven prophylaxis study -- the Konkle study that had been rejected by the FDA. Not only did Novo pay kickbacks[35] to have the very favorable MASAC guidelines issued, it paid for KOLs to author CME articles that bolstered the status of the MASAC guidelines -- effectively making them the automatic "standard of care,"[36] a ploy it had

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[35] 'ProPublica's Dollars for Docs, https://projects.propublica.org/docdollars/, reporting Novo payments to Craig Kessler, MASAC Chair, in 2013.

[36] *See, e.g.*, Shapiro, et al., *Hemophilia and Managed Care: Partnering to Achieve Cost-Effective Care*, The American Journal of Pharmacy Benefits • September/October 2011 (funded by Novo grant and stating, at 252, "Issued in the form of recommendations, MASAC guidelines set the standard of care for HTCs and other providers around the world.").

already used in Europe by creating the Haemophilia Forum "to explore the possibility of consensus recommendations . . . beyond the scope of the current label."

171. When the HTRS Registry received data on off-label NovoSeven® prescriptions for prophylaxis or high-dose use, Novo would commission a "scholarly" article or a Continuing Medical Education ("CME") seminar on the topic.

172. Novo often used the Blood CME Center,[37] which hosted some of Novo's CME seminars, as a conduit to market its off-label prophylaxis message. For example, in or about August 7, 2013, Novo sponsored a CME through Blood CME Center entitled "Hemophilia Experts Video Summit: How We Manage the Musculoskeletal Complications of Hemophilia in Pediatric Patients." The abstract for the CME focuses on prophylaxis, stating that its educational objectives include

> [d]iscuss[ing] current evidence-based data and expert opinion on the ***use of prophylaxis*** in hemophilia patients . . . . Describ[ing] trends and emerging issues relevant to ***prophylactic treatment*** of patients with or at risk for developing inhibitors. Discuss[ing] the ***prophylactic . . . use*** of bypassing agents in pediatric patients . . . and [instructing doctors on how to] [p]rovide appropriate counsel and education for patients and their families about ***prophylaxis*** . . . .

(emphasis added).

173. This CME was not unique: in or about September 18, 2013, Novo sponsored a CME entitled "Prophylactic Bypassing Therapy in Pediatric Inhibitor

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[37] The Blood CME Center is a web-based educational platform owned and operated by Educational Concepts in Medicine, L.L.C. ("ECM"), which operates under grants from multiple pharmaceutical companies including Novo. It also partners with, among others, the HTRS. Grants – as was the case with the two Novo CMEs discussed above – appear to be subject-matter specific rather than blind.

Patients to Avoid Musculoskeletal Complications." Each of these CMEs, paid for by Novo, included among its educational objectives instructing doctors on prophylaxis as a treatment regimen and how to counsel families and patients on accepting and using prophylaxis as a treatment regimen.

174. Novo has also paid for and written multiple articles from 2000 to the present authored by David Cooper and other Novo employees and consultants with KOLs that reflected NovoSeven® favorably and downplayed its weaknesses. It even had an entire department of medical writers, called "Strategic Scientific Communications," that was devoted to drafting such articles.

175. For example, Novo disseminated the Konkle study from 2007 to physicians and referenced it in other publications to support prophylaxis use and suggest it was a universally accepted standard of care despite the fact that the FDA rejected this study in 2006.

176. Novo frequently had physicians who had little or no input into the article sign on as co-authors. Such authorships were considered perks by many physicians because of the increased visibility and stature they provided. Many of these articles promoted off-label prophylaxis and high doses of NovoSeven® and were published in *Haemophilia*, the official journal of the World Federation of Hemophilia and HTRS, whose editor, Craig Kessler, is a Novo KOL.

177. Many of these articles use HTRS data and substitute anecdotal facts for legitimate clinical study data to support off-label uses promoted by Novo. At internal meetings, David Cooper discussed data from the HTRS Registry that were later used to

publish many of these articles. Relator was asked to review abstracts before they were presented at scientific meetings. The abstracts were later turned into published manuscripts using physicians' names as authors. She was aware that these abstracts were scientifically insufficient to support any of the uses discussed and reported her concerns to Levy, but he was powerless to stop the production and publication of these articles.

178. Defendant – through sales representatives' dealings or otherwise – was not truthful about the deficiencies in the science supporting the articles, did not fully disclose the true authorship or Defendant's complete involvement, and/or used them in an otherwise dishonest and untruthful manner.

179. Below is a partial listing of articles promoting the off-label use of NovoSeven® for prophylaxis and/or in high doses well above the amount approved in the drug's package insert that were generated in the foregoing ways:

- AD Shapiro, *Recombinant factor VIIa in the treatment of bleeding in hemophilic children with inhibitors*, Semin Thromb Hemost, 2000, at 26(4):413-19
- A Shapiro, *Inhibitor treatment; state of the art*, Semin Hematol, Oct. 2001, at 26-34
- S Seremetis, *Dose optimization of recombinant factor VIIa in the treatment of acute bleeding in haemophilia-associated inhibitors*, Blood Coagul Fibrinolysis, June 2003, at 14 Suppl 1:S29-30
- G Kenet, A Lubetsky, J Luboshitz, and U Martinowitz, *A new approach to treatment of bleeding episodes in young hemophilia patients: a single bolus megadose of recombinant activated factor VII (NovoSeven®)*, Journal of Thrombosis and Haemostasis, 2003, 1:450-455.
- TC Abshire, *Dose optimization of recombinant factor VIIa for control of mild to moderate bleeds in inhibitor patients: Improved*

efficacy with higher dosing, Semin Hematol, Jan. 2004, at 41(1 Suppl 1:3-7).

- R Parameswaran, AD Shapiro, JC Gill, CM Kessler and HTRS Registry Investigators, *Dose effect and efficacy of rFVIIa in the treatment of haemophilia patients with inhibitors: analysis from the Hemophilia and Thrombosis Research Society Registry,* Haemophilia, Mar. (2005), 11(2):100-6

- R Mehta, R Parameswaran, and AD Shapiro, *An overview of the history, clinical practice concerns, comparative studies and strategies to optimize therapy of bypassing agents*, Haemophilia (2006), 12 (Suppl. 6), 54–61

- E Santagostino, ME Mancuso, A Rocino, G Mancuso, F Scaraggi, and PM Mannucci, *A prospective randomized trial of high and standard dosages of recombinant factor VIIa for treatment of hemarthroses in hemophiliacs with inhibitors*. Journal of Thrombosis and Haemostasis, 2006, 4: 367-371

- G Kenet, *High-dose recombinant factor VIIa therapy in hemophilia patients with inhibitors,* Semin Hematol, Jan. 2006, at 43(1 Suppl 1):S108-10

- K Kavakli, M Makris, B Zulfikar, E Erhardtsen, Zs Abrams, and G Kenet, *Home treatment of haemarthroses using a single dose regimen of recombinant activated factor VII in patients with haemophilia and inhibitors. A multi-centre, randomised, double-blind, cross-over trial*, Journal of Thrombosis and Haemostasis, 95: 600-605

- BA Konkle, LS Ebbesen, E Eehardtson, RP Bianco, T Lissitchkov, L Rusen and MA Serban, *Randomized, prospective clinical trial of recombinant factor VIIa for secondary prophylaxis in hemophilia patients with inhibitors*, Journal of Thrombosis and Hemostasis, 2007, 5:1904-1913

- G Kenet and U Martinowitz, *Single-dose recombinant activated factor VII therapy in hemophilia patients with inhibitors*, Semin Hematol, Apr. 2008, at 45(2 Suppl 1):S38-41

- WK Hoots, LS Ebbesen, BA Konkle, GK Auerswald, HR Roberts, J. Weatherall, JM Ferran, RC Ljung and Novoseven (F7HAEM-1505) Investigators, *Secondary prophylaxis with recombinant activated*

factor VII improves health-related quality of life of haemophilia patients with inhibitors, Haemophilia, May 2008, at 14(3):466-75

- AD Shapiro, *Single-dose recombinant activated factor VII for the treatment of joint bleeds in hemophilia patients with inhibitors,* CLIN ADV Hematol Oncol, Aug. 2008 at 6(8):579-86

- T Abshire and G Kenet, *Safety update on the use of recombinant factor VIIa and the treatment of congenital and acquired deficiency of factor VIII or IX with inhibitors,* Haemophilia, Sept. 2008, at 14(5):898-902

- C Nakar, DL Cooper and D DiMichele,[38] *Recombinant activated factor VII safety and efficacy in the treatment of cranial haemorrhage in patients with congenital haemophilia with inhibitors: an analysis of the Hemophilia and Thrombosis Research Society Registry (2004-2008),* Haemophilia, July 1, 2010, at 16(4):625-31

- EJ Neufeld, CM Kessler, JC Gill, CT Wilke, DL Cooper and HTRS Investigators, *Exposure and safety of higher doses of recombinant factor VIIa ≥250 μg kg(-1) in individuals with congenital haemophilia complicated by alloantibody inhibitors: the Haemophilia and Thrombosis Research Society Registry experience (2004-2008,)* Haemophilia, Jul. 2011, at 17(4):650-6

- G Young, G Auerswald, V Jimenez-Yuste, BA Konkle, T Lambert, M. Morfini, E Santagostino and V Blanchette, *When should prophylaxis therapy in inhibitor patients be considered?,* Haemophilia, Sept. 2011, at 17(5):e849-57

- F.R.M.Y. Cassis, F Querol, A Forsyth and A Iorios on Behalf of the Hero International Advisory Board, *Psychosocial aspects of haemophilia: a systematic review of methodologies and findings,* Haemophilia, (2012), 18, el0l-el 14

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[38] Relator recalls that Dr. DiMichele actually took a very active role in writing and editing this manuscript so that it met her own personal standards of authorship. The resulting comments and background information presented in the manuscript are supported appropriately. This article is an outlier in that respect from the others mentioned above. Notably, David Cooper complained openly about Dr. DiMichele's role. In the other manuscripts that were in progress when Relator was at the company, Cooper and Novo writers were often given *carte blanche* to craft the manuscript.

- AL Forsyth, et al., *Difficult clinical challenges in haemophilia: international experiential perspectives,* Haemophilia (2012), 18 (Suppl. 5), 39-45

- G Young, AD Shapiro, CE Walsh, RA Gruppo, RZ Gut and DL Cooper, *Patient/caregiver-reported recombinant factor VIIa (rFVIIa) dosing: home treatment of acute bleeds in the Dosing Observational Study in Hemophilia (DOSE),* Haemophilia, May 2012, at 18(3):392-9

- G Young, DL Cooper, RZ Gut and HTRS Investigators, *Dosing and effectiveness of recombinant activated factor VII (rFVIIA) in congenital haemophilia with inhibitors by bleed type and location: the experience of the Haemophilia and Thrombosis Research Society (HTRS) Registry (2004-2008),* Haemophilia, Nov. 2012, at 18(6):990-6

- G Young, G Auerswald, V Jimenez-Yuste, T Lambert, M Morfini, E Santagostino and V Blanchette, *PRO-PACT: retrospective observational study on the prophylactic use of recombinant factor VIIa in hemophilia patients with inhibitors,* Thromb Res., Dec. 2012, at 130(6):864-70

- RA Gruppo, CM Kessler, EJ Neufeld and DL Cooper, *Assessment of individual dose utilization vs. physician prescribing recommendations for recombinant activated factor VII (rFVIIa) in paediatric and adult patients with congenital haemophilia and alloantibody inhibitors (CHwI): the Dosing Observational Study in Hemophilia (DOSE)*, Haemophilia, Jul. 2013, at 19(4):524-32

- EJ Neufeld, K Saxena, CM Kessler, DL Cooper & HTRS Investigators, *Dosing, efficacy, and safety of recombinant factor VIIa (rFVIIa) in pediatric versus adult patients: the experience of the Hemostasis and Thrombosis Research Society (HTRS) Registry (2004-2008),* Pediatr Blood Cancer, Jul. 2013, at 60(7):1178-83

- AD Shapiro, EJ Neufeld, V Blanchette, P Salaj, RZ Gut and DL Cooper, *Safety of recombinant activated factor VII (rFVIIa) in patients with congenital haemophilia with inhibitors: overall rFVIIa exposure and intervals following high (>240 μg kg^{-1}) rFVIIa doses across clinical trials and registries,* Haemophilia, Jan. 2014, at 20(1):e23-31

- SR Lentz, A Tandra, RZ Gut and DL Cooper, A novel supplemental approach to capturing post-marketing safety information on recombinant factor VIIa in acquired hemophilia: the Acquired Hemophilia Surveillance project, J. of Blood Med., Jan 2014

- J Maahs, J Donkin, M Recht and DL Cooper, *Mixing and administration times of bypassing agents: observations from the Dosing Observational Study in Hemophilia (DOSE)*, J Blood Med, Aug. 20, 2014, at 5:153-6

- M Recht, EJ Neufeld, VR Sharma, CT Soloem, AS Pickard, RZ Gut and DL Cooper, *Impact of acute bleeding on daily activities of patients with congenital hemophilia with inhibitors and their caregivers and families: observations from the Dosing Observational Study in Hemophilia (DOSE)*, Value Health, Sept. 17, 2014, at (6):744-8

180. Not one of these articles resulted from a blinded, randomized, controlled study, which is the "gold standard" used by the FDA to approve drugs. Instead these articles were generated from data from the HTRS Registry and/or other "case reports," which are nothing more than anecdotal accounts of treatment outcomes experienced by one or a few PHIs.

181. Relator was tasked at Novo with reviewing and commenting on early abstracts for some of the articles noted above as well as to review some of the manuscripts that had already been generated by Novo before or immediately after her arrival, such as the 2008 article by Dr. Hoots *et al.* entitled, "Secondary prophylaxis with recombinant activated factor VII improves health-related quality of life of haemophilia patients with inhibitors." When Relator reviewed the abstract for this article, she informed Novo that the quality-of-life data presented did not meet relevant scientific standards and should not have been published.

182. Other articles listed above were written primarily or exclusively by Novo employees, including physicians and non-physicians alike, many of whom had no educational background or experience in hemophilia. For example, Dr. Cooper had been in a neurosurgery residency program and then acquired an MBA prior to being hired by Novo to market NovoSeven®.

183. The articles are rife with vague phrases such as "might," "may," "it has been suggested," and others not used in legitimate scientific journal articles to support statements that in fact lack scientific support. Rather, Relator detected key Novo marketing messages in some of the articles, such as the phrase, "optimization of dosing regimens may be achieved by considering" contained in the 2001 Shapiro article entitled, "Inhibitor treatment; state of the art." This phrase was one of Novo's key off-label messages regarding high doses and prophylaxis. The quality of these studies is so poor and they are so filled with marketing messages that they do not meet FDA guidance related to dissemination. In particular,

- the information they present is not "based on adequate and well controlled clinical investigations";
- the information is not "truthful and not misleading" and it "pose[s] a significant health threat"; and
- the studies were "written, edited, excerpted, or published specifically for, or at the request of, a drug or device manufacturer" or "edited or significantly influenced by a drug or device manufacturer or any individuals having a financial relationship with the manufacturer."

184. Critically, many articles rely on earlier Novo-driven work such as the Konkle Study and the early articles by Dr. Amy Shapiro, a top-twenty Novo KOL

considered to have an international sphere of influence. Although these articles are scientifically deficient, they are cited as if they set forth a universally accepted standard of care, which they did not. Because there are few "gold standard" studies concerning NovoSeven® and the community of hemophilia physicians is particularly small, the influence exerted by Novo's KOLs and other physician authors in these articles cannot be gainsaid.

185. In June 2009, Novo's Clinical Affairs department developed a "Drug Information Letter" ("DI") that addressed the off-label use of NovoSeven® in combination with FEIBA (called "sequential use") to distribute to physicians. DIs are sometimes generated legitimately by pharmaceutical companies to help physicians who have genuine questions about using drugs off-label, especially in exigent medical situations. However, often DIs are used simply to cloak marketing messages that are used by sales and marketing representatives to push off-label use. The latter applies here, where David Cooper insisted that "marketing and medical affairs" be given the opportunity to review the letter (with "med affairs as co-primary reviewers"). Cooper pushed to have the DI prepared in time for an upcoming sales and marketing "Plan of Action Meeting." Cooper wanted to use the DI to "educate the MSLs." In addition, Cooper pushed to have the DI omit reference to thrombotic adverse events that had either occurred in the clinical trials or had been reported in the post-marketing database. The clear message to be provided was that NovoSeven® did not have a thrombotic safety issue when given to patients with hemophilia. Instead, all thrombotic events were attributed to its competitor FEIBA.

6. Novo Offered Physicians Kickbacks to Encourage Prophylactic and High-Dose Use of NovoSeven®

186. In addition to paying physicians to submit information to the HTRS Registry and write or sign "studies" written or edited by Novo to support off-label uses of NovoSeven®, Novo paid its top twenty KOLs $3,000 each just to complete a profile.

187. Novo also sponsored "consensus meetings" or "roundtable discussion meetings" where experts selected by Novo were to "collaborate" on best practices. Each roundtable participant was paid travel and honoraria expenses by Novo. Novo coordinated the meeting and assigned topic areas to each of the participating experts in order to control the outcome and recommendations of the meeting. Some of the hemophilia physicians participating in these roundtable discussion meetings were also designated as KOLs by Novo. Novo paid KOLs not only to participate in roundtable discussions and lend their names to articles written or co-authored with Novo employees but also to influence prescription writing of other physicians.

188. The KOL kickback program was developed during Relator's tenure at the company. As part of these efforts, Novo's marketing department developed, *inter alia*, a KOL plan and a small glossy booklet summarizing important information about each KOL to assist Novo sales representatives and other marketing professionals when marketing NovoSeven® to other professionals or when entertaining the KOLs.

189. Novo paid its top KOLs handsomely for travel and lodging, consulting, acting as a promotional speaker, and food and beverage. Below is a chart reflecting some

of the payments made in later years, as reported in ProPublica's Dollars for Docs, https://projects.propublica.org/docdollars/.[39]

Key Opinion Leader*	2013	2014	2015	2016	Total
TAMMUELLA E CHRISENTERY-SINGLETON	$ 37,003	$ 70,168	$ 113,726	$ 94,628	$ 315,525
CRAIG KESSLER	$ 51,329	$ 77,692	$ 62,996	$ 43,415	$ 235,432
MIGUEL A ESCOBAR	$ 33,145	$ 69,031	$ 66,835	$ 58,615	$ 227,626
GUY A YOUNG	$ 30,044	$ 56,804	$ 30,510	$ 64,268	$ 181,626
DORIS QUON	$ 23,335	$ 30,273	$ 78,671	$ 49,055	$ 181,334
DIANE NUGENT	$ 17,314	$ 15,159	$ 61,832	$ 21,776	$ 116,081
ROSHNI KULKARNI	$ 42,875	$ 36,129	$ 25,366	$ 11,583	$ 115,953
CLAUDIO SANDOVAL	$ -	$ 1,235	$ 57,257	$ 39,242	$ 97,734
STEVEN W PIPE	$ 16,952	$ 47,073	$ 13,709	$ 5,622	$ 83,356
ALICE MA	$ 5,318	$ 32,005	$ 21,170	$ 5,171	$ 63,664
WILLIAM K HOOTS	$ 9,964	N/A	N/A	$ 16,248	$ 26,212

*Payments are for consulting, travel and lodging, food and beverage, or promotional speaking

190. Internal Novo documents show that by 2012 one Novo KOL was writing $10.2 million dollars a year in prescriptions for NovoSeven®. To Defendant, this doctor was a rock star. Novo made the doctor a key opinion leader without rigorously considering his actual abilities in the practice of medicine. Several years later, the doctor's license was revoked. Yet, while he was still licensed, he was the perfect KOL.

191. Novo also used study grants, speaker engagements, advisory boards, and funding to secure the loyalty of KOLs or convince uncooperative physicians to use NovoSeven®. In an internal email in 2009, Relator questioned a grant given to Novo

[39] See Dollars for Docs, published by ProPublica, https://projects.propublica.org/docdollars/

KOL Dr. Valentino by Medical Affairs. She was informed that Dr. Valentino had received more money from other manufacturers and that Novo needed to "keep up with the Joneses" and pay him the amount requested. The amount was not based upon merit. Similarly, Novo agreed to pay the $30,000 per patient requested by the Robert Wood Johnson center for participation in a clinical trial, which was practically twice the amount requested by the other centers and would have been a direct violation of good clinical practices.

192. KOLs were also sent to all-expenses-paid high-level meetings where Novo ostensibly sought their experience with NovoSeven® and "guidance" for future uses. In reality, Novo showered money and other remuneration on the KOLs so that they would use or continue to use large quantities of NovoSeven® either by recommending prophylaxis to their patients or prescribing high doses. An added benefit to the payments made to KOLs was that Novo could use their prescribing habits to convince other doctors to use NovoSeven® in the same ways.

193. For example, in 2001, prior to working for Novo, Relator, who was not a KOL, was invited by Novo to a symposium in Copenhagen at which she was reimbursed for her travel and lodging and was paid an honorarium of about $5,000 to learn about off-label uses for NovoSeven®. The symposium was predominately about NovoSeven®'s expected use for trauma surgery for non-hemophilia patients[40] and CNS (central nervous system) bleeding, but also included a lecture to the community of hemophilia physicians

[40] This off-label use was the subject of Novo's 2011 False Claims Act settlement of more than $25 million.

by Dr. Gilit Kenet, who presented her limited data on the use of "megadose" NovoSeven® to control bleeding episodes in a few of her pediatric PHIs. This was the first time that Relator had learned about Novo's intent to market NovoSeven® in doses that were larger than indicated by the label. Relator recalled that, at the time, the lecture seemed to present ground-breaking data in the treatment of these patients, but it was never able to be replicated or substantiated, thus FDA did not provide the updated label. The purpose of the payments and remuneration were not only to secure prescriptions but also served as an off-label marketing vehicle for Novo.

194. Likewise, in one three-month period in 2013, Novo paid KOL Dr. Craig Kessler more than $34,000 in expenses, honoraria, and other remuneration.[41] Dr. Kessler is a Professor at Georgetown University Medical Center in the Departments of Medicine and Pathology *and* served as Chair of the Medical and Scientific Advisory Council ("MASAC") for the National Hemophilia Foundation from 2007 to 2015. During the same three months in 2013, MASAC released guidance recommending the use of bypassing agents, including NovoSeven®, for prophylaxis. With regard to prophylactic use of NovoSeven®, the only study the MASAC guidance relies on is the Konkle Study that was rejected by the FDA years ago.

195. Further, the length of service on MASAC's board by other physicians who had significant ties to Novo is striking. For example, Novo KOL Dr. Keith Hoots served as the Chair of MASAC from 2001 to 2006. Following Dr. Kessler's chairmanship, Dr.

[41] According to ProPublica's Dollars for Docs, Kessler was paid at least $235,432 by Novo between 2013-2016.

Steven Pipe became the Chair in 2015. Dr. Pipe received more than $83,000 from Novo between 2013 and 2016.

196. Novo directed its kickbacks to large hemophilia centers as well. A May 2009 PowerPoint discusses a multi-faceted marketing scheme directed at large hemophilia centers referred to as the "Novo Nordisk Global Hemophilia Network." The PowerPoint describes how Novo will recruit 40-50 large centers of excellence for "long term collaboration" on trials, "publication participation," scientific meetings, speaker's training, medical writing and invitations to advisory boards. Novo's "support" of the centers of excellence may include "flexible/tailored individual payment structure, constant flow of trials ... input to clinical development, advisory board, publications."

7. Novo Violated and Made False Statements With Regard to its CIA

197. On May 26, 2011, Defendant and its counsel executed a Corporate Integrity Agreement (CIA) with the Office of Inspector General of the Department of Health and Human Services.[42] That agreement continued to be in effect until 2016. A stated purpose of the agreement was to promote compliance with the very statutes and regulations that Relator allege were routinely violated. Compliance with said regulations was material to the government paying for any of Defendant's products including NovoSeven®; this is why the CIA was executed.

[42] *See* https://www.justice.gov/opa/pr/danish-pharmaceutical-novo-nordisk-pay-25-million-resolve-allegations-label-promotion

198. Pursuant to the requirements of the CIA, Defendant and its representatives signed and filed with the government certifications of compliance. For example, on May 21, 2013, Defendant's agent Michael Ferrara, the "Brand Director, Hemophilia," signed a certification filed with the Government which stated:

> I am the Brand Director, Hemophilia. I have been trained on and understand the compliance requirements and responsibilities as they relate to the marketing of Hemophilia products including NovoSeven an area under my supervision. My job responsibilities include ensuring compliance with regard to the marketing of Hemophilia products including NovoSeven with all applicable Federal health care program requirements, FDA requirements, obligations of the Corporate Integrity Agreement, and NNI policies, and I have taken steps to promote such compliance. In the event that I have identified potential issues of noncompliance with these requirements, I have referred all such issues consistent with NNI processes for reporting potential misconduct for further review and follow-up. Apart from those referred issues, I am not currently aware of any violations of applicable Federal health care program requirements, FDA requirements, requirements of the Corporate Integrity Agreement, or the requirements of NNI policies. I understand that this certification is being provided to and relied upon by the United States.

199. The above certification was false. Defendant filed or caused to be filed multiple certifications similar to the Ferrara certification. Each one was false. The filing of these certifications was a condition of receiving government reimbursement for Defendant's products.

200. In addition to the above, it is significant that the defendant falsely certified compliance with its own rules, including those governing gifts and benefits to patients, which this Consolidated Complaint alleges were repeatedly violated.

201. The following people also falsely certified compliance with the CIA:

Name	Position	Date
Gruhn, Jerzy	President, North America	5/22/2013
Williams, Edward	Corporate Vice President, Biopharmaceuticals	5/22/2013

Grote, Gary	Vice President, Market Access, Biopharmaceuticals	5/28/2013
Hill, Tanya	Vice President, Hemophilia Marketing	5/21/13

VII. HARMS ASSOCIATED WITH THE USE OF NOVOSEVEN® FOR PROPHYLAXIS OR IN HIGH-DOSE REGIMENS

202. The use of NovoSeven® in prophylaxis and in high doses is not benign. In 1994 researchers reported on two factor VIII-deficient patients with inhibitors. The one who received the highest doses of NovoSeven® (up to 135 μg/kg, 45 μg/kg above the FDA-approved dose of 90 μg/kg), appeared to suffer "a cerebral vascular accident" (that is, a stroke). (ML Schmidt, S Gamerman, HE Smith, JP Scott, and DM DiMichele, *Recombinant activated factor VII (rFVIIa) therapy for intracranial hemorrhage in hemophilia A patients with inhibitors*, Am. J. Hematol. 1994 Sep;47(1):36-40). In 1999, researchers reported three instances of thromboembolic events ("TEs"), that is, clots where and when they should not occur, occurring in a population of 28 patients treated with NovoSeven®. These three events occurred in two patients "being treated for a serious bleeding episode" and would have required multiple and frequent doses given beyond the standard dosing scheme as approved by the FDA. Events such as these raised early concerns regarding unrestrained dosing and frequency of the treatment. (I Scharrer, *Recombinant factor VIIa for patients with inhibitors to factor VIII or IX or factor VII deficiency*, Haemophilia (1999), 5, 253-259).

203. In 2006, the FDA published an article in JAMA[43] reviewing the 185 TEs associated with NovoSeven® that had been reported to the agency's Adverse Event

[43] *See* KA O'Connell, et al., Thromboembolic Adverse Events After Use of Recombinant

Reporting System ("AERS") from March 1999, when NovoSeven® was first approved, through December 31, 2004. Although 151 of the 185 TEs involved non-hemophilia patients using NovoSeven®, there were several hemophilia patients who experienced TEs as well, indicating that PHIs who use NovoSeven® are not without risk. Moreover, since AERS is a voluntary system of reporting, the FDA notes that its database likely undercounts the true number of thromboembolisms as often times treating physicians will consider the event to be an expected adverse event under the clinical circumstances.

204. The most recent safety review (EJ Neufeld, C Négrier, S Benchikh el Fegoun, DL Cooper, A Rojas-Rios, S Seremetis, *Recombinant activated factor VII in approved indications: Update on safety*, Haemophilia, 2018;1–3), reported that 91 patients with congenital hemophilia with inhibitors had a thrombotic episode resulting in 11 fatalities, 14 who did not recover, and 15 with unknown outcome.

205. Indeed, by at least 2010, the FDA specifically mandated that Novo put a black box warning in the package insert to warn of increased risks of TEs when NovoSeven® is used off-label. The FDA also required the black box to emphasize that "**[s]afety and efficacy of NovoSeven RT has not been established outside the approved indication**" (emphasis in the original). Further, in Section 5.3 the label advised that "Precautions should be exercised when NovoSeven® RT is used for prolonged dosing," with a reference to Section 2.2, which stated, "the biological and

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Human Coagulation Factor VIIa, JAMA, January 18, 2006 - Vol. 295, No. 3.

clinical effects of prolonged elevated levels of Factor VIIa have not been studied; therefore, the duration of post-hemostatic dosing should be minimized."

206. The current package insert[44] no longer contains the language quoted above, but the black box warning still exists for thrombosis, now without qualification. Further, the black box warning encourages physicians to "[d]iscuss the risks [of thrombosis] and explain the signs and symptoms of thrombotic and thromboembolic events to patients who will receive NovoSevenRT®."

207. There is another serious safety problem associated with using NovoSeven® for prophylaxis and in high doses. All factors are administered intravenously and for some patients that requires an indwelling line or catheter. The catheter itself increases the risk of TEs and this is compounded by the infusion of a bypassing agent such as NovoSeven®, particularly if given in high doses or on a daily basis for "prophylaxis," as described in Novo publications. Moreover, all these lines must go through the skin, which is covered with bacteria. If care is not meticulous at all times, bacteria can move down the central line and enter the systemic circulation, causing serious infection. The longer a line is in and the more often it is accessed, the higher the risk of infection. Of note, the more recent safety publications have not included any data on catheter-associated thrombotic events or infectious complications.

[44] *See* https://www.fda.gov/media/70442/download.

208. By 2009, at the very latest, Novo knew that single doses above the approved 90 μg/kg were no more effective than single doses of 90 μg/kg. It also knew that thrombotic events were occurring with repeated dosing, prolonged use, and higher doses of NovoSeven®.[45] Indeed, in 2009, Novo acknowledged to the FDA that there was an "increased risk" of "[s]erious thrombotic adverse events associated with the use of NovoSeven . . . [w]hen administered outside approved indications." But Relator has determined that Novo downplayed these facts and skewed the data it was publishing by omitting critical details and suppressing instances of thrombotic and other adverse events.

209. Novo has continued to maintain that the use of NovoSeven® in single high doses and for daily prophylactic use provides a substantial improvement in clinical benefit with very low risk of TEs. There is still no randomized controlled evidence for either claim and no FDA approval for either of these indications.

210. For example, one article cited above, T. Abshire and G. Kenet, Recombinant factor VIIa: review of efficacy, dosing regimens and safety in patients with congenital and acquired factor VIII or IX inhibitors, J Thromb. Haemost 2004; 2: 899–909.2 ("Abshire (2004)"), was a purported safety review on the use of NovoSeven®. The article is based on data from several unidentified "studies" and "spontaneous" reports (meaning the reports were "volunteered") provided by Novo Nordisk, which also provided "editorial assistance." *Id.* at 907. Although the reports and the underlying study

[45] *See, e.g.*, 2006 label, available at https://www.fda.gov/media/70435/download (explaining that patients with adverse effect generally had 12 doses or more); NNICID-1226050 (2009 Novo evaluation of thrombotic risk); NNICID-1073387, at 2 (2009 letter to FDA seeking to change black box warning mandated by FDA).

show serious adverse effects from the use of NovoSeven®, up to and including death, the authors point to the patients' co-morbid conditions in order to dismiss the events as unrelated to hemophilia with inhibitors or NovoSeven®. Indeed, not one of the patients' complications is said to have been linked to the use of NovoSeven®. The list of cases, however, does not support the authors' conclusions that (1) the probability of thrombosis is "very low" (2) NovoSeven® is "safer" than other bypassing agents, or (3) "high dose" is more efficacious than the indicated dose.

211. The authors, both Novo KOLs at the time, picked up the Novo messaging by stating that most of the patients who experienced a TE associated with NovoSeven® infusion already had other predisposing conditions that could explain this adverse event. But this discussion lumps patients with quite different disorders together.[46] The TEs reported for congenital hemophiliacs should have raised a "red flag" suggesting that a therapeutic agent – *i.e.*, the NovoSeven® – was the cause.

212. Abshire and Kenet also echoed Novo marketing messages about high-dose use, stating that "evidence is accumulating that initial bolus doses in excess of 200 μg/kg^{-1} may result in better hemostatic control."[47] Further, the authors claim, "Importantly, no

[46] In particular, the discussion lumps congenital PHI together with acquired PHI even though they are quite different disorders. Acquired hemophilia is quite rare and often occurs in elderly patients with multiple medical problems that carry added risk for these patients when treated with a bypassing agent, such as NovoSeven®.

[47] Abshire and Kenet even suggest they can apply statistical assessments to this registry data and cite to a registry study that concluded that "higher dosing (>200 μg kg^{-1} per dose) was more efficacious compared with lower dosing schedules (<200 μg kg^{-1} per dose) at a highly significant level (high dose, 97%; low dose, 84%; $P < 0.001$)." Applying statistical assessments "after the fact" and without controls, however, is not

thrombosis was seen with the higher dosing schedule" and "there does not appear to be any increase in thrombotic events related to dosage or dosing frequency." even though the publication's tables of reported TEs show congenital patients who had been given single doses larger than the FDA approved dose.

213. Several of the claims made in the Abshire and Kenet article were challenged in a subsequent letter to the editor by two well respected hemophilia physicians (J Teitel, MC Poon, *The safety of recombinant factor VIIa: a rebuttal*, J Thromb Haemost 2004; 2: 2078) who raised a concern that, "by emphasizing the paucity of spontaneous reports of thrombotic events post licensure, [Abshire and Kenet] may be inadvertently leading readers to underestimate this complication." The authors also asserted that there likely had been additional TEs not reported by the article: "Based on information shared freely by the manufacturer at various meetings in recent years, it seems likely that the seven events shown in Abshire and Kenet's Table 2 do not represent all the thrombotic complications that occurred in clinical trials of rFVIIa."

214. In fact, Relator is aware of patients who experienced thrombotic events who are not included in this study. For example, in reviewing the FDA's database as it relates to the reporting of thrombotic events, Relator noted that a five-year-old boy suffered from a transient ischemic attack (*i.e.*, a stroke) from taking NovoSeven® in 1991. The report of this incident was published in 1994 and received by Novo in 2006, but was not reported by Novo until 2018.

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considered valid.

215. Poon and Teitel also assert that there is "no available data" to support Abshire and Kenet's claim that the risk of TE in inhibitor patients was lower with NovoSeven® than for similar agents. While Poon and Teitel chalk the problems with Abshire (2004) up to mere oversight, it is undisputed that this manuscript was edited by a company that stood to gain from a lopsided analysis.[48]

216. Unfortunately, this was one of the last public critiques of Novo's manipulation of the data and use of publications for marketing purposes. Drs. Teitel and Poon eventually became spokesmen for the company in different capacities.

217. More recently, at the American Society of Hematology Annual Meeting in December 2018, there was a poster presentation titled "Thrombotic Events with NovoSeven® RT in Approved Indications Are Rare (0.2%) and Associated with Older Age (>= 65 y), Cardiovascular Disease, and Concomitant Use of aPCCs." Although the title and abstract plainly seek to attribute TEs to predisposing factors other than NovoSeven®, of the 88 PHIs noted, only 10.2% were elderly, 34.1% had received concomitant aPCCs, and 9.1% had cardiovascular disease. Therefore, despite what the title suggests, the majority of the PHIs who had a TE had ***no*** identifiable underlying risk factor other than NovoSeven® administration; nor did the authors identify whether these patients had been treated with high dose and/or prophylaxis therapy.

[48] "[T]he statement that in inhibitor patients this risk 'appears to be lower than the thrombotic risk seen with other clotting factor concentrates with known thrombogenic potential' is not supported by available data."

218. By promoting NovoSeven® off-label for prophylaxis and in high doses and downplaying the potential harms such treatments present, Novo is putting patients who already suffer from a debilitating disease at serious risk without any proven prospect of benefit. Yet Novo continues to this day to make the same false and misleading claims, even in the face of conflicting or non-existent data.

VIII. THE HIGH COST OF FACTORS

219. Factors are quite expensive – NovoSeven® especially so – and much of the cost is borne by federal and state governments' Medicare Part B and Medicaid programs. According to a 2013 report by the Medicaid Health Plans of America,[49] approximately one third of patients with hemophilia are covered through state Medicaid programs. Likewise, a 2011 study showed that more than 40% of the 3380 young men and boys with severe hemophilia studied were covered by Medicare and Medicaid.[50]

220. As shown below, Medicare, Medicaid, and the State of Washington have paid billions of dollars for NovoSeven® over the last decade:

	Medicare Spend	No. of Patients	Spend per Patient
2017	$ 116,100,933	220	$ 527,732
2016	$ 111,544,564	200	$ 557,723
2015	$ 98,562,071	187	$ 527,070
2014	$ 108,850,454	176	$ 618,468
2013	$ 117,488,828	225	$ 522,173

[49] Addressing the Needs of Members with Hemophilia in Medicaid Managed Care: Issues and Implications for Health Plans, Medicaid Health Plans of America Clinical Brief, July 22, 2013.

[50] JR Baker et al., *Insurance, Home Therapy, and Prophylaxis in U.S. Youth with Severe Hemophilia*, Am. J. Prev. Med. 2001; 41 (6S4), p. S340 at Table 1. The study also stated, "Participants insured by Medicare were significantly more likely to use prophylaxis than were those insured by commercial plans." *Id.* at p. S340 (in the text).

2012	$ 111,544,564	200	$ 557,722
2011	$ 130,809,189	220	$ 594,587
2010*	$ 100,000,000		
2009*	$ 100,000,000		
2008*	$ 100,000,000		
Total	**$ 1,094,900,603**		

Source: CMS Historical Medicare Part B data , *https://www.cms.gov/Research-Statistics-Data-and- Systems/Statistics-Trends-and-Reports/Information-on- Prescription-Drugs/index*
* Conservative estimates based on CMS data for 2011-2017

	Medicaid Spend	Washington
2017	$ 293,878,672	$ 5,683,434.13
2016	$ 274,813,947	$ 2,235,486.23
2015	$ 298,183,999	$ 2,084,896.20
2014	$ 231,169,540	$ 3,857,048.51
2013	$ 219,524,142	$ 9,693,961.41
2012	$ 214,688,850	$ 8,504,664.97
2011	$ 192,416,704	$ 9,547,737.29
2010*	$ 180,000,000	$ 15,278,012.54
2009*	$ 150,000,000	$ 21,696,250.19
2008*	$ 120,000,000	$ 16,291,080.14
Total	$ **2,174,675,854**	**$ 94,872,571.61**

Source: CMS Historical Medicaid data, *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on- Prescription-Drugs/index*
* Conservative estimates based on CMS data for 2011-2017
*Washington data based on claims submitted to the Washington Medicaid program.

221. An HHS OIG report issued in October 2011[51] found that Medicare paid $46,349,026 to the Indiana Hemophilia and Thrombosis Center for NovoSeven®, reportedly used as indicated by a total of six patients over two years. That comes to approximately $4 million per patient per year.

222. Damages in this case were also incurred by Tri-Care, public employee health and welfare funds, and private-pay health insurance companies. The Medicaid Health Plans of America study also shows that more than 51% of hemophilia patients were covered by "commercial insurance." The impact is far-reaching: in justifying its failure to reduce its spending as requested by City Council, the Philadelphia Department of Prisons cited its hemophilia patient population as one reason it was unable to do so. It noted that one inmate required $100,000 of hemophilia medication each month.

223. Not surprisingly, the high cost of hemophilia treatments is the source of significant revenue for health care providers as well. Providers such as the 135 federally funded Hemophilia Treatment Centers ("HTCs"),[52] doctors, and home health care companies, buy clotting factors from the manufacturers at wholesale, but charge the patients' insurers, including Medicare and Medicaid, full retail. This markup allows providers to profit from each unit they prescribe.

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[51] Review of Medicare Payments for NovoSeven Coagulation Factor VIIa to Indiana Hemophilia and Thrombosis Center, Inc. from January 1, 2008 through December 31, 2009, Department of Health and Human Services' Office of Inspector General, October 2011 (A-05-11-00027).

[52] These HTCs reportedly treat 30,000 patients with coagulation disorders like hemophilia.

224. Moreover, the markup for Medicare is particularly large because of another federal program called the 340B Discount Drug Pricing Program ("340B").[53] Under 340B, manufacturers are required to sell factors at a significant discount from their usual wholesale price to HTCs and other hemophilia providers that receive federal funding. As covered entities, HTCs are permitted to use pharmacy income from 340B only to support patient health, education, and supportive services, including clinical staff. Medicare pays providers, however, the same retail price whether the providers have used 340B or not, generating a significantly increased profit.

225. Because of the high profit margin, providers like HTCs have an incentive to prescribe NovoSeven® and other hemophilia factors to patients insured through Medicare or private insurance at higher and more frequent doses than are medically necessary. In such instances, the drug manufacturer and providers profit, while Medicare (or private insurance) winds up paying for treatments that would otherwise not have been prescribed. The amount of revenue generated by 340B participation can be significant.

226. For example, the Indiana HTC that was reviewed in 2011 by OIG, which is headed by Novo KOL Dr. Amy Shapiro, reported that 340B revenue accounted for about 97% of its total budget and was used to support all of its program operations.[54] This is the same HTC that received $46 million from Medicare for treating six patients with NovoSeven® for two years. Notably, its IRS Form 990 for 2016 reported that it had

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[54] Indeed, a survey of HTCs and 340B pricing published in 2018 reported that for the majority of respondents, 340B income supports 90% of the staff and support activities.

more than $100 million in gross sales and held more than $110 million in net assets. While the structure of the 340B program contemplates that some covered entities may benefit from the spread between discounted drug prices and reimbursement drug prices, 340B-covered entities are not exempt from either the Stark Act or the Anti-Kickback Statute.[55]

227. Under certain circumstances, providers may also be able to use 340B to buy factors for their Medicaid patients. However, if they do, the state Medicaid programs cannot obtain rebates from manufacturers that they would otherwise be entitled to. (This would amount to a "double discount" from the manufacturer, which is specifically prohibited by 340B.) So providers generally do not use 340B for patients with hemophilia on Medicaid.

228. Medical supply companies, called home health care companies ("HHCCs"), that provide factor to patients with hemophilia also benefit from increased use of NovoSeven®: they too earn profits based upon their volume of sales of factor. While HHCCs do not qualify for 340B discounts, their arrangements with Novo for purchase of NovoSeven® do generate significant profits like those of the HTCs and other providers.

229. A 2003 GAO Report estimates that HHCCs receive discounts of 22 to 40 percent below average wholesale price ("AWP"). For this reason, the increased use (or overuse) of factor is so lucrative for HHCCs that some companies hire patients with hemophilia to recruit other patients with hemophilia to use factor for prophylaxis or at

[55] OIG Advisory Request No. 98-15, https://oig.hhs.gov/fraud/docs/advisoryopinions/1998/ao98_15.htm

higher doses. Finding hemophilia patients to promote prophylaxis to other patients is not difficult in a small community of patients closely tied together by support groups based on their unusual, severe common problem.

230. In short, overuse of factor has a tremendous effect on all health care plans, including those funded by the government and by private insurers.

IX. NOVO'S UNLAWFUL PROMOTION AND PAYMENT OF KICKBACKS ARE MATERIAL TO THE GOVERNMENT

231. As explained above, to be subject to FCA liability, a defendant's false claims or statements must be material to the government. In *Universal Health Servs. v. United States ex rel. Escobar*, __ U.S. __, 136 S. Ct. 1989, 2002 (2016), the Supreme Court confirmed that the test for materiality under the FCA is whether the false or fraudulent claims or statements have the tendency to influence the government's decisions. *See also* 31 U.S.C. § 3729(b)(4) (defining "material" to mean "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property").

232. Novo's misconduct, as alleged in this Consolidated Complaint, would plainly be material to the government's decisions to reimburse Medicare and Medicaid claims for off-label uses of NovoSeven®. To begin with, CMS has consistently denounced off-label promotion, elucidated its dangers, and produced guidance documents explaining how to recognize it.

233. Moreover, the government has consistently invoked the FCA as the statutory mechanism to recover money for off-label claims that were wrongfully paid

while concurrently prosecuting off-label promotion like Novo's through criminal misbranding statutes. Continued pursuit of these cases upon credible evidence of a violation is highly probative of materiality.

234. In addition, numerous appellate courts have held that compliance with the Anti-Kickback Statute is a condition of payment for Medicare and Medicaid. In addition, the 2010 Affordable Care Act amendments to the Anti-Kickback Statute establish that violations of the Anti-Kickback Statute are *per se* violations of the FCA. Thus, they are necessarily material to the government's decision to pay claims. So, too, were pre-2010 violations of the Anti-Kickback Statute.

235. Unfortunately, many of CMS's concerns have manifested in this case. As set forth above, Novo promoted unsafe and unproven off-label uses of NovoSeven® for both adults and children. Early, inadequate studies sponsored by Novo or written by Novo KOLs, together with the MASAC guidance discussed above, had a snowball effect that – when combined with the small group of hemophilia doctors, Novo's kickbacks to patients and doctors, the lucrative nature of prophylaxis and high dosing – turned prophylaxis and higher doses into the standard of care despite the absence of clinical evidence to support the safety and efficacy of such uses.

X. COUNTS

COUNT ONE
Brought by Relator
Federal False Claims Act, 31 U.S.C. § 3729(a)(1)(A)[56]

236. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Consolidated Complaint.

237. This is a claim for treble damages and civil penalties under the False Claims Act, 31 U.S.C. § 3729(a)(1)(A).

238. By virtue of the misrepresentations, off-label promotion, kickbacks, beneficiary inducements, and submission of non-reimbursable claims described above, Defendant knowingly presented, or caused to be presented, false or fraudulent claims for payment or approval of prescriptions for Novo7.

239. The United States, unaware of the false or fraudulent nature of the claims that Defendant caused to be submitted, paid for claims that otherwise would not have been allowed.

240. By reason of these payments, the United States has been damaged, and continues to be damaged, in a substantial amount.

[56] To the extent wrongdoing occurred prior to May 20, 2009, this Consolidated Complaint should be deemed to include violations of the Federal False Claims Act prior to its recent amendments, *e.g.* 31 U.S.C. § 3730(a)(1) (1986).

COUNT TWO
Brought by Relator
Federal False Claims Act, 31 U.S.C. § 3729(a)(1)(B)[57]

241. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Consolidated Complaint.

242. This is a claim for treble damages and civil penalties under the False Claims Act, 31 U.S.C. § 3729(a)(1)(B).

243. By virtue of the misrepresentations, off-label promotion, kickbacks, beneficiary inducements, and submission of non-reimbursable claims described above, Defendant knowingly made, used, or caused to be made or used, a false record(s) or statement(s) material to a false or fraudulent claim with regard to prescriptions for Novo7.

244. The United States, unaware of the false or fraudulent nature of the claims that Defendant caused to be submitted, paid for claims that otherwise would not have been allowed.

245. By reason of these payments, the United States has been damaged, and continues to be damaged, in a substantial amount.

[57] To the extent wrongdoing occurred prior to May 20, 2009, this Consolidated Complaint should be deemed to include violations of the Federal False Claims Act prior to its recent amendments, *e.g.* 31 U.S.C. § 3730(a)(2).

COUNT THREE
Brought by Relator
California False Claims Act, Cal. Gov't Code §§ 12650 *et seq.*

246. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Consolidated Complaint.

247. This is a claim for treble damages and civil penalties under the California False Claims Act, Cal. Gov't Code §§ 12650 *et seq.*

248. By virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant knowingly presented or caused to be presented to the California Medicaid Program (*i.e.*, Medi-Cal) false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made or used, a false record or statement.

249. Moreover by virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant conspired to commit violations of the California False Claims Act.

250. The California Medicaid Program, unaware of the false or fraudulent nature of the claims Defendant caused to be submitted, paid for claims that otherwise would not have been allowed.

251. By reason of these payments, the California Medicaid Program has been damaged, and continues to be damaged, in a substantial amount.

COUNT FOUR
Brought by Relator
California Insurance Frauds Prevention Act,
Cal. Ins. Code § 1871.7

252. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Consolidated Complaint.

253. This is a claim for treble damages and civil penalties under the California Insurance Frauds Prevention Act, Cal. Ins. Code § 1871.7.

254. By virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant caused to be presented, or knowingly assisted or conspired in presenting or causing to be presented, to the insurers in the State of California fraudulent claims that were induced by payments of kickbacks to physicians, in violation of California Penal Code § 550(b)(1), among other provisions.

255. Moreover, by virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant knowingly caused to be made fraudulent bills intended to be presented to the insurers in connection with, or in support of, claims for the payment of compensation under contracts of insurance knowing that the statements contained false or misleading information concerning material facts, in violation of California Penal Code § 550(b)(2), among other provisions.

256. By virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant knowingly presented or caused to be presented false or fraudulent claims for the payment of a loss or injury, including payment of a loss or injury under a contract of insurance; prepared, made, and subscribed

writings, with the intent to present or use them, or to allow them to be presented, in support of false or fraudulent claims; and made or caused to be made false or fraudulent claims for payment of a health care benefit in violation of California Penal Code § 550(a)(1), (5), and (6), among other provisions.

257. By virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant caused false claims to be submitted to insurance companies for the payment of health care benefits. Had the private insurance companies known that prescriptions for Defendant's drugs had been written because physicians had been paid kickbacks by Defendant to do so and/or that Defendant had made statements containing false or misleading information concerning facts material to such prescriptions, these companies would not have provided reimbursement for these prescriptions.

258. By virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant's conduct represents the inducement of health care benefits through a pattern and practice of fraudulent conduct and constitutes false claims within the meaning of Cal. Ins. Code § 1871.7(b) and Sections 549 & 550(a)(6) of the California Penal Code, among other provisions.

259. By reason of these payments, insurers have been damaged, and continue to be damaged, in a substantial amount.

COUNT FIVE
Brought by Relator
Colorado Medicaid False Claims Act,
Colo. Rev. Stat. §§ 25.5-4-303.5, et seq.

260. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Consolidated Complaint.

261. This is a claim for treble damages and civil penalties under the Colorado Medicaid False Claims Act, Colo. Rev. Stat. §§ 25.5-4-303.5, *et seq.*

262. By virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant knowingly presented or caused to be presented to the Colorado Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made or used, a false record or statement.

263. Moreover by virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant conspired to commit violations of the Colorado False Claims Act.

264. The Colorado Medicaid Program, unaware of the false or fraudulent nature of the claims Defendant caused to be submitted, paid for claims that otherwise would not have been allowed.

265. By reason of these payments, the Colorado Medicaid Program has been damaged, and continues to be damaged, in a substantial amount.

COUNT SIX
Brought by Relator
Connecticut False Claims Act,
Conn. Gen. Stat. §§ 17b-301a -17b301p (2010 Supplement)[58]

266. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Consolidated Complaint.

267. This is a claim for treble damages and civil penalties under the Connecticut False Claims Act, Conn. Gen. Stat. §§ 17b-301a - 17b-301p (2010 Supplement).

268. By virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant knowingly presented or caused to be presented to the Connecticut Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made or used, a false record or statement.

269. Moreover by virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant conspired to commit violations of the Connecticut False Claims Act.

270. The Connecticut Medicaid Program, unaware of the false or fraudulent nature of the claims Defendant caused to be submitted, paid for claims that otherwise would not have been allowed.

[58] Connecticut General Statute §§ 17b-301a-17b301p was repealed by the legislature by Public Act No. 14-217, effective July 1, 2014, and was replaced by an expanded version of the Connecticut False Claims Act, but the expanded version has not yet been codified. *See* http://www.cga.ct.gov/2014/act/pa/pdf/2014PA-00217-R00HB-05597-PA.pdf.

271. By reason of these payments, the Connecticut Medicaid Program has been damaged, and continues to be damaged, in a substantial amount.

COUNT SEVEN
Brought by Relator
Delaware False Claims And Reporting Act, 6 Del. Code §§ 1201 *et seq.*

272. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Consolidated Complaint.

273. This is a claim for treble damages and civil penalties under the Delaware False Claims And Reporting Act, 6 Del. Code §§ 1201 *et seq*.

274. By virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant knowingly presented or caused to be presented to the Delaware Medicaid program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made or used, a false record or statement.

275. Moreover by virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant conspired to commit violations of the Delaware False Claims Act.

276. The Delaware Medicaid Program, unaware of the false or fraudulent nature of the claims Defendant caused to be submitted, paid for claims that otherwise would not have been allowed.

277. By reason of these payments, the Delaware Medicaid Program has been damaged, and continues to be damaged, in a substantial amount.

COUNT EIGHT
Brought by Relator
Florida False Claims Act, Fla. Stat. Ann. §§ 68.081 *et seq.*

278. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Consolidated Complaint.

279. This is a claim for treble damages and civil penalties under the Florida False Claims Act, Fla. Stat. Ann. §§ 68.081 *et seq.*

280. By virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant knowingly presented or caused to be presented to the Florida Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made or used, a false record or statement.

281. Moreover by virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant conspired to commit violations of the Florida False Claims Act.

282. The Florida Medicaid Program, unaware of the false or fraudulent nature of the claims Defendant caused to be submitted, paid for claims that otherwise would not have been allowed.

283. By reason of these payments, the Florida Medicaid Program has been damaged, and continues to be damaged, in a substantial amount.

COUNT NINE
Brought by Relator
Georgia False Medicaid Claims Act, Ga. Code Ann. §§ 49-4-168 *et seq.*

284. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Consolidated Complaint.

285. This is a claim for treble damages and civil penalties under the Georgia False Medicaid Claims Act, Ga. Code Ann. §§ 49-4-168 *et seq.*

286. By virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant knowingly presented or caused to be presented to the Georgia Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made or used, a false record or statement.

287. Moreover by virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant conspired to commit violations of the Georgia False Medicaid Claims Act.

288. The Georgia Medicaid Program, unaware of the false or fraudulent nature of the claims Defendant caused to be submitted, paid for claims that otherwise would not have been allowed.

289. By reason of these payments, the Georgia Medicaid Program has been damaged, and continues to be damaged, in a substantial amount.

COUNT TEN
Brought by Relator
Hawaii False Claims Act, Haw. Rev. Stat. §§ 661-21 *et seq.*

290. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Consolidated Complaint.

291. This is a claim for treble damages and civil penalties under the Hawaii False Claims Act, Haw. Rev. Stat. §§ 661-21 *et seq.*

292. By virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant knowingly presented or caused to be presented to the Hawaii Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using or causing to be made or used, a false record or statement.

293. Moreover by virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant conspired to commit violations of the Hawaii False Claims Act.

294. The Hawaii Medicaid Program, unaware of the false or fraudulent nature of the claims Defendant caused to be submitted, paid for claims that otherwise would not have been allowed.

295. By reason of these payments, the Hawaii Medicaid Program has been damaged, and continues to be damaged, in a substantial amount.

COUNT ELEVEN
Brought by Relator
Illinois False Claims Act,
740 Ill. Comp. Stat. 175/1 *et seq.*

296. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Consolidated Complaint.

297. This is a claim for treble damages and civil penalties under the Illinois False Claims Act, 740 Ill. Comp. Stat. 175/1 *et seq*.

298. By virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant knowingly presented or caused to be presented to the Illinois Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made or used, a false record or statement.

299. Moreover by virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendant conspired to commit violations of the Illinois Whistleblower Reward and Protection Act.

300. The Illinois Medicaid Program, unaware of the false or fraudulent nature of the claims Defendant caused to be submitted, paid for claims that otherwise would not have been allowed.

301. By reason of these payments, the Illinois Medicaid Program has been damaged, and continues to be damaged, in a substantial amount.

COUNT TWELVE
Brought by Relator
Indiana False Claims and Whistleblower Protection Act,
Ind. Code §§ 5-11-5.5-1 *et seq.*

302. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Consolidated Complaint.

303. This is a claim for treble damages and civil penalties under the Indiana False Claims and Whistleblower Protection Act, Ind. Code §§ 5-11-5.5-1 *et seq*.

304. By virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant knowingly presented or caused to be presented to the Indiana Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made or used, a false record or statement.

305. Moreover by virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant conspired to commit violations of the Indiana False Claims and Whistleblower Protection Act.

306. The Indiana Medicaid Program, unaware of the false or fraudulent nature of the claims Defendant caused to be submitted, paid for claims that otherwise would not have been allowed.

307. By reason of these payments, the Indiana Medicaid Program has been damaged, and continues to be damaged, in a substantial amount.

COUNT THIRTEEN
Brought by Relator
Iowa False Claims Law,
Iowa Code §§ 685.1 *et seq.*

308. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Consolidated Complaint.

309. This is a claim for treble damages and civil penalties under the Iowa False Claims Law, Iowa Code §§ 685.1 *et seq.*

310. By virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant knowingly presented or caused to be presented to the Iowa Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made or used, a false record or statement.

311. Moreover by virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant conspired to commit violations of the Iowa False Claims Act.

312. The Iowa Medicaid Program, unaware of the false or fraudulent nature of the claims Defendant caused to be submitted, paid for claims that otherwise would not have been allowed.

313. By reason of these payments, the Iowa Medicaid Program has been damaged, and continues to be damaged, in a substantial amount.

COUNT FOURTEEN
Brought by Relator
Louisiana Medical Assistance Programs Integrity Law,
La. Rev. Stat. §§ 46:437.1 *et seq.*

314. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Consolidated Complaint.

315. This is a claim for treble damages and civil penalties under the Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. §§ 46:437.1 *et seq.*

316. By virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant knowingly presented or caused to be presented to the Louisiana Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made or used, a false record or statement.

317. Moreover by virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant conspired to commit violations of the Louisiana Medical Assistance Programs Integrity Law.

318. The Louisiana Medicaid Program, unaware of the false or fraudulent nature of the claims Defendant caused to be submitted, paid for claims that otherwise would not have been allowed.

319. By reason of these payments, the Louisiana Medicaid Program has been damaged, and continues to be damaged, in a substantial amount.

COUNT FIFTEEN
Brought by Relator
Maryland False Health Claims Act of 2010,
Md. Health Code Ann. §§ 2-601 *et seq.*

320. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Consolidated Complaint.

321. This is a claim for treble damages and civil penalties under the Maryland False Health Claims Act, Md. Health Code Ann. §§ 2-601 *et seq.*

322. By virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant knowingly presented or caused to be presented to the Maryland Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made or used, a false record or statement.

323. Moreover by virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant conspired to commit violations of the Maryland False Health Claims Act.

324. The Maryland Medicaid Program, unaware of the false or fraudulent nature of the claims Defendant caused to be submitted, paid for claims that otherwise would not have been allowed.

325. By reason of these payments, the Maryland Medicaid Program has been damaged, and continues to be damaged, in a substantial amount.

COUNT SIXTEEN
Brought by Relator
Massachusetts False Claims Law, Mass. Ann. Laws Ch. 12, § 5A-5*O*

326. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Consolidated Complaint.

327. This is a claim for treble damages and civil penalties under the Massachusetts False Claims Law, Mass. Ann. Laws Ch. 12, § 5A-5O.

328. By virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant knowingly presented or caused to be presented to the Massachusetts Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made, or used a false record or statement.

329. Moreover by virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendant conspired to commit violations of the Massachusetts False Claims Act.

330. The Massachusetts Medicaid Program, unaware of the false or fraudulent nature of the claims Defendant caused to be submitted, paid for claims that otherwise would not have been allowed.

331. By reason of these payments, the Massachusetts Medicaid Program has been damaged, and continues to be damaged, in a substantial amount.

COUNT SEVENTEEN
Brought by Relator
Michigan Medicaid False Claim Act, M.C.L.A. §§ 400.601 *et seq.*

332. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Consolidated Complaint.

333. This is a claim for treble damages and civil penalties under the Michigan Medicaid False Claim Act, M.C.L.A. §§ 400.601 *et seq.*

334. By virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant knowingly presented or caused to be presented to the Michigan Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made or used, a false record or statement.

335. Moreover by virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendant conspired to commit violations of the Michigan Medicaid False Claims Act.

336. The Michigan Medicaid Program, unaware of the false or fraudulent nature of the claims Defendant caused to be submitted, paid for claims that otherwise would not have been allowed.

337. By reason of these payments, the Michigan Medicaid Program has been damaged, and continues to be damaged, in a substantial amount.

COUNT EIGHTEEN
Brought by Relator
Minnesota Fraudulent State Claims Act, Minn. Stat. §§ 15C.01 *et seq.*

338. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Consolidated Complaint.

339. This is a claim for treble damages and civil penalties under the Minnesota Fraudulent State Claims Act, Minn. Stat. §§ 15C.01 *et seq.*

340. By virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant knowingly presented or caused to be presented to the Minnesota Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made or used, a false record or statement.

341. Moreover by virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant conspired to commit violations of the Minnesota False Claims Act.

342. The Minnesota Medicaid Program, unaware of the false or fraudulent nature of the claims Defendant caused to be submitted, paid for claims that otherwise would not have been allowed.

343. By reason of these payments, the Minnesota Medicaid Program has been damaged, and continues to be damaged, in a substantial amount.

COUNT NINETEEN
Brought by Relator
Montana False Claims Act, Mont. Code Ann. §§ 17-8-401 *et seq.*

344. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Consolidated Complaint.

345. This is a claim for treble damages and civil penalties under the Montana False Claims Act, Mont. Code Ann. §§ 17-8-401 *et seq.*

346. By virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant knowingly presented or caused to be presented to the Montana Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made or used, a false record or statement.

347. Moreover by virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant conspired to commit violations of the Montana False Claims Act.

348. The Montana Medicaid Program, unaware of the false or fraudulent nature of the claims Defendant caused to be submitted, paid for claims that otherwise would not have been allowed.

349. By reason of these payments, the Montana Medicaid Program has been damaged, and continues to be damaged, in a substantial amount.

COUNT TWENTY
Brought by Relator
Nevada False Claims Act, Nev. Rev. Stat. §§ 357.010 *et seq.*

350. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Consolidated Complaint.

351. This is a claim for treble damages and civil penalties under the Nevada False Claims Act, Nev. Rev. Stat. §§ 357.010 *et seq.*

352. By virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant knowingly presented or caused to be presented to the Nevada Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made or used, a false record or statement.

353. Moreover by virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant conspired to commit violations of the Nevada False Claims Act.

354. The Nevada Medicaid Program, unaware of the false or fraudulent nature of the claims Defendant caused to be submitted, paid for claims that otherwise would not have been allowed.

355. By reason of these payments, the Nevada Medicaid Program has been damaged, and continues to be damaged, in a substantial amount.

COUNT TWENTY-ONE
Brought by Relator
New Hampshire Medicaid Fraud and False Claims,
N.H. Rev. Stat. Ann. §§ 167:61 et seq.

1. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Consolidated Complaint.

2. This is a claim for treble damages and civil penalties under the New Hampshire Medicaid Fraud and False Claims, N.H. Rev. Stat. Ann. §§ 167:61 *et seq.*

356. By virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant knowingly presented or caused to be presented to the New Hampshire Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made or used, a false record or statement.

357. Moreover by virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant conspired to commit violations of the New Hampshire Medicaid Fraud and False Claims Act.

358. The Nevada Medicaid Program, unaware of the false or fraudulent nature of the claims Defendant caused to be submitted, paid for claims that otherwise would not have been allowed.

359. By reason of these payments, the Nevada Medicaid Program has been damaged, and continues to be damaged, in a substantial amount.

COUNT TWENTY-TWO
Brought by Relator
New Jersey False Claims Act, N.J. Stat. §§ 2A:32C-1 *et seq.*

360. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Consolidated Complaint.

361. This is a claim for treble damages and civil penalties under the New Jersey False Claims Act, N.J. Stat. §§ 2A:32C-1 *et seq*.

362. By virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant knowingly presented or caused to be presented to the New Jersey Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made or used, a false record or statement.

363. Moreover by virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant conspired to commit violations of the New Jersey False Claims Act.

364. The New Jersey Medicaid Program, unaware of the false or fraudulent nature of the claims Defendant caused to be submitted, paid for claims that otherwise would not have been allowed.

365. By reason of these payments, the New Jersey Medicaid Program has been damaged, and continues to be damaged, in a substantial amount.

COUNT TWENTY-THREE
Brought by Relator
New Mexico Medicaid False Claims Act,
N.M. Stat. Ann. 1978, §§ 27-14-1 *et seq.*

366. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Consolidated Complaint..

367. This is a claim for treble damages and civil penalties under the New Mexico Medicaid False Claims Act, N.M. Stat. Ann. 1978, §§ 27-14-1 *et seq*.

368. By virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant knowingly presented or caused to be presented to the New Mexico Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made or used, a false record or statement.

369. Moreover by virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant conspired to commit violations of the New Mexico Medicaid False Claims Act.

370. The New Mexico Medicaid Program, unaware of the false or fraudulent nature of the claims Defendant caused to be submitted, paid for claims that otherwise would not have been allowed.

371. By reason of these payments, the New Mexico Medicaid Program has been damaged, and continues to be damaged, in a substantial amount.

COUNT TWENTY-FOUR
Brought by Relator
New York False Claims Act, N.Y. State Fin. Law §§ 187 *et seq.*

372. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Consolidated Complaint.

373. This is a claim for treble damages and civil penalties under the New York False Claims Act, N.Y. State Fin. Law §§ 187 *et seq*.

374. By virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant knowingly presented or caused to be presented to the New York Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made or used, a false record or statement.

375. Moreover by virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant conspired to commit violations of the New York False Claims Act.

376. The New York Medicaid Program, unaware of the false or fraudulent nature of the claims Defendant caused to be submitted, paid for claims that otherwise would not have been allowed.

377. By reason of these payments, the New York Medicaid Program has been damaged, and continues to be damaged, in a substantial amount.

COUNT TWENTY-FIVE
Brought by Relator
North Carolina False Claims Act, N.C. Gen. Stat. §§ 1-605 *et seq.*

378. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Consolidated Complaint.

379. This is a claim for treble damages and civil penalties under the North Carolina False Claims Act, 52 N.C. Gen. Stat. §§ 1-605 *et seq.*

380. By virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant knowingly presented or caused to be presented to the North Carolina Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made or used, a false record or statement.

381. Moreover by virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant conspired to commit violations of the North Carolina False Claims Act.

382. The North Carolina Medicaid Program, unaware of the false or fraudulent nature of the claims Defendant caused to be submitted, paid for claims that otherwise would not have been allowed.

383. By reason of these payments, the North Carolina Medicaid Program has been damaged, and continues to be damaged, in a substantial amount.

COUNT TWENTY-SIX
Brought by Relator
Oklahoma Medicaid False Claims Act, 63 Okl. St. §§ 5053 *et seq.*

384. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Consolidated Complaint.

385. This is a claim for treble damages and civil penalties under the Oklahoma Medicaid False Claims Act, 63 Okl. St. §§ 5053 *et seq*.

386. By virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant knowingly presented or caused to be presented to the Oklahoma Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made or used, a false record or statement.

387. Moreover by virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant conspired to commit violations of the Oklahoma Medicaid False Claims Act.

388. The Oklahoma Medicaid Program, unaware of the false or fraudulent nature of the claims Defendant caused to be submitted, paid for claims that otherwise would not have been allowed.

389. By reason of these payments, the Oklahoma Medicaid Program has been damaged, and continues to be damaged, in a substantial amount.

COUNT TWENTY-SEVEN
Brought by Relator
Rhode Island State False Claims Act, R.I. Gen. Laws 1956, §§ 9-1.1-1 *et seq.*

390. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Consolidated Complaint.

391. This is a claim for treble damages and civil penalties under the Rhode Island State False Claims Act, R.I. Gen. Laws 1956, §§ 9-1.1-1 *et seq.*

392. By virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant knowingly presented or caused to be presented to the Rhode Island Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by using or causing to be used or made, a false record or statement.

393. Moreover by virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant conspired to commit violations of the Rhode Island False Claims Act.

394. The Rhode Island Medicaid Program, unaware of the false or fraudulent nature of the claims Defendant caused to be submitted, paid for claims that otherwise would not have been allowed.

395. By reason of these payments, the Rhode Island Medicaid Program has been damaged, and continues to be damaged, in a substantial amount.

COUNT TWENTY-EIGHT
Brought by Relator
Tennessee Medicaid False Claims Act,
Tenn. Code Ann. §§ 71-5-181 *et seq.*

396. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Consolidated Complaint.

397. This is a claim for treble damages and civil penalties under the Tennessee Medicaid False Claims Act, Tenn. Code Ann. §§ 71-5-181 *et seq*.

398. By virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant knowingly presented or caused to be presented to the Tennessee Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made or used, a false record or statement.

399. Moreover by virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant conspired to commit violations of the Tennessee Medicaid False Claims Act and the Tennessee False Claims Act.

400. The Tennessee Medicaid Program, unaware of the false or fraudulent nature of the claims Defendant caused to be submitted, paid for claims that otherwise would not have been allowed.

401. By reason of these payments, the Tennessee Medicaid Program has been damaged, and continues to be damaged, in a substantial amount.

COUNT TWENTY-NINE
Brought by Relator
Texas Medicaid Fraud Prevention Act,
Tex. Hum. Res. Code Ann. §§ 36.001 *et seq.*

402. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Consolidated Complaint.

403. This is a claim for treble damages and civil penalties under the Texas Medicaid Fraud Prevention Act, Tex. Hum. Res. Code Ann. § 36.001 *et seq.*

404. By virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant knowingly presented or caused to be presented to the Texas Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made or used, a false record or statement.

405. Moreover by virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant conspired to commit violations of the Texas Medicaid Fraud Prevention Act.

406. The Texas Medicaid Program, unaware of the false or fraudulent nature of the claims Defendant caused to be submitted, paid for claims that otherwise would not have been allowed.

407. By reason of these payments, the Texas Medicaid Program has been damaged, and continues to be damaged, in a substantial amount.

COUNT THIRTY
Brought by Relator
Virginia Fraud Against Taxpayers Act,
Va. Code Ann. §§ 8.01-216.1 *et seq.*

408. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Consolidated Complaint.

409. This is a claim for treble damages and civil penalties under the Virginia Fraud Against Taxpayers Act, Va. Code Ann. §§ 8.01-216.1 *et seq.*

410. By virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant knowingly presented or caused to be presented to the Virginia Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made or used, a false record or statement.

411. Moreover by virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant conspired to commit violations of the Virginia Fraud Against Taxpayers Act.

412. The Virginia Medicaid Program, unaware of the false or fraudulent nature of the claims Defendant caused to be submitted, paid for claims that otherwise would not have been allowed.

413. By reason of these payments, the Virginia Medicaid Program has been damaged, and continues to be damaged, in a substantial amount.

COUNT THIRTY-ONE
Brought by the State of Washington and Relator
Washington Medicaid Fraud False Claims Act
Rev. Code Wash. §§ 74.66.005 *et seq.*

414. Washington and Relator re-allege and incorporate by reference the allegations contained in the preceding paragraphs of this Consolidated Complaint.

415. This is a claim for treble damages and civil penalties under the Washington Medicaid Fraud False Claims Act, Rev. Code Wash. §§ 74.66.005 *et seq.*

416. By virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant knowingly presented or caused to be presented to the Washington Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made or used, a false record or statement.

417. Moreover by virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant conspired to commit violations of the Washington Medicaid Fraud False Claims Act.

418. The Washington Medicaid Program, unaware of the false or fraudulent nature of the claims Defendant caused to be submitted, paid for claims that otherwise would not have been allowed.

419. By reason of these payments, the Washington Medicaid Program has been damaged, and continues to be damaged, in a substantial amount.

COUNT THIRTY-TWO
Brought by the State of Washington
Washington Fraudulent Practices Act, Rev. Code Wash. §74.09.210

420. Washington re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Consolidated Complaint.

421. RCW 74.09.210(1)(a),(b) and (c) makes liable for the repayment of any excess benefits or payments received, plus interest, any person or legal entity that shall "[o]n behalf of himself or herself *or others*, obtain or attempt to obtain benefits or payments under this chapter in a greater amount than that to which entitled by means of: (a) A willful false statement . . . .", (b) By willful misrepresentation, or by concealment of any material facts; . . . ."; (c) By other fraudulent scheme or device . . . ." (Emphasis added).

422. As a result of Novo's off-label marketing, kickbacks and offers of kickbacks to induce the purchase of, to order, and/or to recommend NovoSeven® in violation of the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(2) and the laws, rules and regulations applicable to the Washington Medicaid Program, including its provider manuals, willful false statements, misrepresentations, concealment of material facts or other fraudulent schemes were made in conjunction with false and fraudulent claims for payment made to the State of Washington. Novo, on behalf of itself and others knowingly obtained or attempted to obtain benefits or payments under RCW Chapter 74.09.210 in an amount greater than that to which either was entitled by inducing a willful false statement(s). The false records or statements or omissions were false certifications, representations, or omissions, that the services and/or supplies were

provided in compliance with all applicable Federal and State laws and regulations, including but not limited to the Federal Anti-Kickback regulations and statutes and the laws, rules and regulations of the Washington Medicaid program, including its provider manuals.

423. By virtue of the willful false statements Novo knowingly caused to be submitted, pursuant to RCW 74.09.210(2), Novo is liable to the State of Washington for repayment of the excess benefits or payments received, plus interest, and civil penalties in an amount not to exceed three times the amount of such excess benefits or payments.

COUNT THIRTY-THREE
Brought by Relator
Wisconsin False Claims For Medical Assistance Act,
Wis. Stat. §§ 20.931 *et seq.*

424. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Consolidated Complaint.

425. This is a claim for treble damages and civil penalties under the Wisconsin False Claims For Medical Assistance Act, Wis. Stat. §§ 20.931 *et seq.*

426. By virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant knowingly presented or caused to be presented to the Wisconsin Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made or used, a false record or statement.

427. Moreover by virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant conspired to commit violations of the Wisconsin False Claims Act.

428. The Wisconsin Medicaid Program, unaware of the false or fraudulent nature of the claims Defendant caused to be submitted, paid for claims that otherwise would not have been allowed.

429. By reason of these payments, the Wisconsin Medicaid Program has been damaged, and continues to be damaged, in a substantial amount.

COUNT THIRTY-FOUR
Brought by Relator
District of Columbia False Claims Act,
D.C. Code §§ 2-381.02 *et seq.*

430. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Consolidated Complaint.

431. This is a claim for treble damages and civil penalties under the District of Columbia False Claims Act, D.C. Code §§ 2-381.02 *et seq.*

432. By virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant knowingly presented or caused to be presented to the District of Columbia Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by using or causing to be used or made, a false record or statement.

433. Moreover by virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant conspired to commit violations of the District of Columbia False Claims Act.

434. The District of Columbia Medicaid Program, unaware of the false or fraudulent nature of the claims Defendant caused to be submitted, paid for claims that otherwise would not have been allowed.

435. By reason of these payments, the District of Columbia Medicaid Program has been damaged, and continues to be damaged, in a substantial amount.

COUNT THIRTY-FIVE
Brought by Relator
City of Chicago False Claims Act,
Chicago Mun. Code Chapter 1-22-010, *et seq.*

436. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Consolidated Complaint.

437. This is a claim for treble damages and civil penalties under the City of Chicago False Claims Act, Chicago Municipal Code Chapter 1-22-010, *et seq.*

438. By virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant knowingly presented or caused to be presented to the City of Chicago false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by using or causing to be used or made, a false record or statement.

439. Moreover by virtue of the kickbacks, misrepresentations, and submissions of non-reimbursable claims described above, Defendant conspired to commit violations of the City of Chicago False Claims Act.

440. The City of Chicago, unaware of the false or fraudulent nature of the claims Defendant caused to be submitted, paid for claims that otherwise would not have been allowed.

441. By reason of these payments, the City of Chicago has been damaged, and continues to be damaged, in a substantial amount.

XI. PRAYER FOR RELIEF

WHEREFORE, Relator requests that judgment be entered against Defendant, ordering that:

a. Defendant cease and desist from violating the False Claims Act, 31 U.S.C. §§ 3729 *et seq.*, the State and Municipal False Claims Acts, and the California Insurance Frauds Prevention Act;

b. Defendant pay not less than $10,781 and not more than $21,563[59] for each violation of 31 U.S.C. § 3729, plus three times the amount of damages the United States has sustained because of Defendant's actions, plus the appropriate amount to the States and Municipalities under similar provisions of their False Claims Acts;

[59] As adjusted in accordance with the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015. *See* 84 FR 13520 (DOJ 2019) (available at https://www.govinfo.gov/content/pkg/FR-2019-04-05/pdf/FR-2019-04-05.pdf) (making final civil penalties set in interim final rule in 2016, *see* 81 FR 42491 (DOJ 2016)).

c. Defendant pay not less than $5,000 and not more than $10,000 for each and every fraudulent claim for compensation Defendant caused to be submitted in violation of the California Insurance Frauds Prevention Act, plus an assessment not more than three times the amount of each claim;

d. The Relator be awarded the maximum "relator's share" allowed pursuant to 31 U.S.C. § 3730(d) and similar provisions of the State and Municipal False Claims Acts and the California Insurance Frauds Prevention Act;

e. The Relator be awarded all costs of this action, including attorneys' fees and costs pursuant to 31 U.S.C. § 3730(d) and similar provisions of the State False Claims Acts and the California Insurance Frauds Prevention Act;

f. Defendant be enjoined from concealing, removing, encumbering or disposing of assets that may be required to pay the damages and civil monetary penalties imposed by the Court;

g. Defendant disgorge all sums by which it has been enriched unjustly by its wrongful conduct; and

h. The United States, the States, Municipalities and the Relator recover such other relief as the Court deems just and proper.

REQUEST FOR TRIAL BY JURY

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, the State of Washington and Relator hereby demand a trial by jury.

//

Dated: May 11, 2020

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CERTIFICATE OF SERVICE

I hereby certify that a copy of this Second Consolidated Complaint will be served, via first class mail, upon the following persons as soon as possible after a file-stamped copy is received from the Clerk's Office.

s/ Michael Burrage
Michael Burrage

VIA FIRST CLASS MAIL

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